

**PROPOSAL FOR FDA TO ISSUE AN ORDER FOR DEVICE REPAIR,
REPLACEMENT, AND/OR REFUND**

NOTICE OF OPPORTUNITY FOR A HEARING

VIA EMAIL

May 2, 2022

Thomas J. Fallon
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Dear Mr. Fallon,

As you are aware, on June 14, 2021, Philips Respironics, Inc. (Philips) initiated a Class I recall of certain ventilators, continuous positive airway pressure (CPAP) machines, and bilevel positive airway pressure (BiPAP) machines.¹ This letter is to inform Philips that the U.S. Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) is proposing that an order should be issued pursuant to section 518(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360h(b), to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated. In accordance with section 518(b), CDRH hereby provides Philips with notice of an opportunity for an informal hearing under 21 C.F.R. Part 16 on CDRH's proposal that a section 518(b) order should be issued, the grounds for which are described below.

Section 518(b) of the FD&C Act authorizes FDA² to issue an order requiring the manufacturer of a device to submit a plan to (i) repair the device so that it does not present an unreasonable risk of substantial harm; (ii) replace the device with a like or equivalent device in conformity with all applicable requirements of the FD&C Act; and/or (iii) refund the purchase price of the device (less a reasonable allowance for use if the device has been in possession of the user for one year or more), if FDA determines that certain criteria have been met after affording an opportunity for an informal hearing. Under section 518(b)(1)(A), those criteria are as follows:

¹ These include the following devices, manufactured before April 26, 2021 and distributed in the United States: A-Series BiPAP V30 Auto, C-Series ASV, C-Series S/T and AVAPS, DreamStation, DreamStation ASV, DreamStation Go, DreamStation ST, AVAPS, E30, OmniLab Advanced+, REMstar SE Auto, SystemOne ASV4, SystemOne (Q-Series), Trilogy 100, and Trilogy 200 (ventilator).

² As provided in existing delegations of authority (found in the FDA Staff Manual Guide 1410.10), the Secretary of Health and Human Services has delegated the authority under section 518 to the Commissioner of Food and Drugs.



- (i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health;
- (ii) there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture;
- (iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device; and
- (iv) notification authorized by section 518(a) of the FD&C Act would not by itself be sufficient to eliminate the unreasonable risk, and the repair, replacement, and/or refunding of the purchase price of the device is necessary to eliminate such risk.

As discussed below, the devices recalled by Philips contain a polyester-based polyurethane (PE-PUR) foam that may degrade into particles that may be ingested or inhaled by device users, and/or may emit volatile organic compounds (VOCs) above acceptable thresholds, with potential toxic and carcinogenic effects and other significant harms. CDRH therefore believes that there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health. In addition, CDRH believes that there is sufficient evidence for FDA to determine that there are reasonable grounds to believe that the recalled devices that Philips manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture. CDRH also believes that there is sufficient evidence for FDA to determine that there are reasonable grounds to believe that the risk associated with the devices was not caused by the failure of a person other than Philips to exercise due care in the installation, maintenance, repair, or use of the devices at issue. In particular, although the use of ozone cleaners by device users may have exacerbated degradation of the PE-PUR foam, evidence indicates that the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care. Finally, because patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices, CDRH believes that there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health that the notification ordered pursuant to section 518(a) on March 10, 2022 alone is not sufficient to eliminate, and that repairing, replacing and/or issuing a refund for the affected devices is necessary.

Under section 518(b), if, after Philips has been afforded an opportunity for an informal hearing, FDA makes the four determinations described above, an order may be issued to require Philips, as the manufacturer of the devices at issue, to submit a plan to repair, replace, and/or refund the purchase price for the recalled devices that were manufactured after November 2015. This



notice of opportunity for a hearing is governed by the regulations in 21 C.F.R. Part 16 (Regulatory Hearing Before the FDA), as will be any regulatory hearing that is held regarding this matter. Such hearing will also be governed by the regulations in 21 C.F.R. Part 10, Subpart C (Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures). Philips has the right to be advised and represented by counsel at all times in connection with any such hearing, and the instructions for requesting a hearing under 21 C.F.R. Part 16 are provided at the end of this letter. **Please note that your request for a hearing must be received by FDA no later than seven (7) calendar days after the date of this letter.** Copies of the regulations contained at 21 C.F.R. Parts 16 and 10, Subpart C, are enclosed for your reference.

Below, we briefly describe the basis for CDRH’s proposal that an order should be issued under section 518(b).

- 1. The recalled devices contain a PE-PUR foam that may degrade and/or emit harmful chemicals, potentially resulting in toxic and carcinogenic effects and other significant harms to device users, and therefore present an unreasonable risk of substantial harm to the public health.*

The PE-PUR foam found in the millions of recalled devices may degrade into particles, which may enter the air pathways of the devices and may be inhaled or ingested by device users. Inhalation or ingestion of these particles may cause toxic and potentially carcinogenic effects, as well as irritation of the respiratory tract, eyes, nose, and skin, asthma, inflammatory responses, and headache. Substantial deposition of fine particle debris may also cause irreversible harm to lung tissues, organ impairment and long-lasting respiratory dysfunction. In addition, Philips’ Health Hazard Evaluations (HHEs) regarding the foam degradation risk reported potential degradation products identified with the recalled devices, including toluene diisocyanate isomers (TDI), toluene diamine isomers (TDA), and diethylene glycol (DEG).³ Philips has acknowledged, and CDRH agrees, that the issues associated with the degradation of the PE-PUR foam found in the recalled devices “can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.”⁴ As Philips concluded in its HHEs regarding the foam degradation risk, “[b]ased on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with [the] conclusion that particles are likely to reach the upper airway and potentially the lower

³ Philips Respironics Health Hazard Evaluation Form ER 2241621 – Foam Degradation in PAP Devices, Version 00, at 6, 8 (Apr. 26, 2021); Philips Respironics Health Hazard Evaluation Form ER 2241622 – Foam Degradation in NIV Devices, Version 01, at 10, 12 (Apr. 26, 2021); Philips Respironics Health Hazard Evaluation Form ER 2241623 – Foam Degradation in Trilogy Devices, Version 00, at 4, 6 (Apr. 26, 2021).

⁴ Philips Respironics, Inc., *URGENT: Medical Device Recall – Philips Respironics Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models*; Philips Respironics, Inc., *URGENT: Medical Device Recall – Philips Respironics CPAP and Bi-Level PAP Devices*.



respiratory track, a reasonable worst-case estimate for the general and higher risk (*e.g.*, patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure.”⁵

On April 25, 2022, Philips shared with FDA a table and accompanying narrative summarizing what Philips identified as the testing related to the PE-PUR foam that had been conducted by or for Philips as of that date. This summary suggested that certain tests that produced results supporting the conclusion that the recalled devices present a significant risk suffered from limitations and should be discounted, and emphasized tests that produced results identifying no risks. However, Philips’ summary included justifications for discounting the previously conducted tests that CDRH does not find persuasive, and Philips excluded from its risk assessment prior tests that showed cytotoxicity failure and compounds of concern. Moreover, even if certain tests suffered from limitations as described in Philips’ summary, the existence of such limitations would not necessarily disprove the existence of risks associated with the PE-PUR foam, but rather would support the need for further testing. Indeed, in its summary, Philips underscores that because a significant amount of testing remains ongoing, Philips cannot confirm that health risks for patients do not exist for potential degradation products, and the overall guidance for patients and providers in the most recent version of Philips’ recall communication remains unchanged.⁶ In a test plan summary provided to FDA on April 26, 2022, Philips further informed FDA that certain test reports are not expected until August 2022, including foam level testing of lab-aged Trilogy 100/200 devices, VOC testing of Trilogy 100/200 field units, particulate matter testing of new A-Series/Omnilab devices, and other testing.⁷ For foam level testing of Trilogy 100/200 field units, the anticipated start date, as of April 26, 2022, is “TBD.”⁸

With respect to the risk involving degradation products in particular, Philips has informed FDA that although Philips does not currently believe TDI to be an expected degradation product of PE-PUR foam, Philips currently understands both TDA and DEG to be potential degradation products of the PE-PUR foam (depending on the extent of degradation), and that Philips ultimately “agree[s] that until conclusive evidence demonstrates that health risks related to degradation products will not exist for patients, [Philips’] current guidance based upon the June 14, 2021 HHE will remain unchanged.”⁹

⁵ Philips Respironics Health Hazard Evaluation Form ER 2241621 – Foam Degradation in PAP Devices, Version 00, at 9 (Apr. 26, 2021); Philips Respironics Health Hazard Evaluation Form ER 2241622 – Foam Degradation in NIV Devices, Version 01, at 13 (Apr. 26, 2021); Philips Respironics Health Hazard Evaluation Form ER 2241623 – Foam Degradation in Trilogy Devices, Version 00, at 7 (Apr. 26, 2021).

⁶ *See, e.g.*, Philips Respironics Summary of PE-PUR Testing Results and Conclusions Available to Date (April 25, 2022).

⁷ Philips Respironics PE-PUR Test Plan Summary, at 8-10 (April 26, 2022).

⁸ *Id.*

⁹ E-mail from Tom Fallon, Head of Quality, Sleep and Respiratory Care, Philips Respironics, Inc., to Dr. Denise Hampton, FDA (Apr. 25, 2022).

In addition, although Philips' HHEs describe a "remote probability" that use of the devices will ultimately cause harm related to foam degradation, they also note that "harm in this case may not be immediately recognizable and may not be something that the customer would/could report," adding that certain harms "may not be easily linked to the hazardous situation or device use in general" – and that in the case of genetic mutations in particular, "a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage."¹⁰

Laboratory testing performed for Philips in 2021 evaluating the biocompatibility of the gas pathway of the DreamStation 1 device has also indicated that certain VOCs may be emitted from the PE-PUR foam above acceptable thresholds per the ISO 18562-3 standard.¹¹ These compounds include dimethyl diazine, phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl), and formaldehyde. Philips has acknowledged that, in a worst-case scenario, exposure to VOCs as a class may cause possible toxic and carcinogenic effects, as well as irritation of the respiratory tract, eyes, nose, and skin, nausea or vomiting, hypersensitivity reactions, dizziness, and headache.¹²

In December 2021, Philips notified FDA of additional testing conducted by third parties indicating that VOCs emitted by the PE-PUR foam in the DreamStation 1 device are below the threshold set by ISO 18562-3.¹³ Based on the results of that testing, Philips updated the HHE regarding DreamStation 1 VOCs to state that the test data currently available do not indicate a correlation between exposure to the detected levels of VOCs and toxic and carcinogenic effects, and to downgrade the estimation of severity of harm from level 3 (crucial) "result[ing] in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment" to level 2 (marginal) "result[ing] in moderate injury: temporary impairment, or self-limiting illness."¹⁴ However, based on the information currently available, Philips' updated risk analysis for VOCs is unpersuasive for several reasons. Philips did not determine the margin of safety for all VOCs emitted as they relate to the affected device users. Moreover, the ISO 18562-3 standard is generally used for evaluating new materials or products on a pre-market basis, and the testing of degraded foam for the emission of VOCs cannot be addressed with reference to the ISO 18562-3 standard alone. Novel continuous sampling of the

¹⁰ Philips Respiroics Health Hazard Evaluation Form ER 2241621 – Foam Degradation in PAP Devices, Version 00, at 13-14 (Apr. 26, 2021); Philips Respiroics Health Hazard Evaluation Form ER 2241622 – Foam Degradation in NIV Devices, Version 01, at 17-18 (Apr. 26, 2021); Philips Respiroics Health Hazard Evaluation Form ER 2241623 – Foam Degradation in Trilogly Devices, Version 00, at 11-12 (Apr. 26, 2021).

¹¹ Philips Respiroics Health Hazard Evaluation Form ER 2242138 – DreamStation 1 Volatile Organic Compounds (VOC), Version 01, at 4 (May 25, 2021).

¹² *Id.* at 7.

¹³ Letter from Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, Philips Respiroics, Inc., to Dr. Malvina Eydelman, FDA, at 1-3 (Dec. 17, 2021).

¹⁴ Philips Respiroics Health Hazard Evaluation Form ER 2242138 – DreamStation 1 Volatile Organic Compounds (VOC), Version 02, at 8-9 (Dec. 14, 2021).



foam as it degrades is necessary to support a toxicological risk assessment. The ISO 18562 standards also do not consider all VOCs that may be emitted, depending on the boiling point of the compound. In addition, as noted above, Philips is conducting further VOC testing, and testing of devices other than the DreamStation 1 remains ongoing.

Based on the risks associated with the potential degradation of, and the VOC emissions from, the PE-PUR foam contained therein, FDA has classified the recall as Class I, indicating a reasonable probability that the use of, or exposure to, the products will cause serious adverse health consequences or death. This risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam. In light of these considerations, CDRH believes that there is sufficient evidence for FDA to determine that the recalled devices present an unreasonable risk of substantial harm to the public health.

2. There are reasonable grounds to believe that the devices were not properly manufactured with reference to the state of the art as it existed at the time of their manufacture.

Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.

In 2015, Philips ^{(b) (4)} Ltd., an entity owned by the parent company of Philips Respironics ^{(b) (4)}, also referred to as ^{(b) (4)}, implemented a preventative maintenance procedure in ^{(b) (4)} to replace the air intake assembly of Trilogy ventilator products, due to complaints that had been received regarding degradation of the PE-PUR foam contained in the products. Based on information provided to FDA during the recent FDA inspection of Philips' manufacturing facility in Murrysville, Pennsylvania, conducted between August 26, 2021, and November 9, 2021, Philips was made aware in 2015 of the implementation of this preventative maintenance procedure by Philips ^{(b) (4)} Ltd. due to Philips ^{(b) (4)} Ltd.'s receipt of complaints. During the inspection, Philips' representatives informed the FDA investigator that all of Philips' communications regarding this issue were conducted over the phone. However, the representatives provided one document, an email from Philips ^{(b) (4)} Ltd. personnel to service personnel in November 2015 regarding the preventative maintenance procedure, which Philips' representatives confirmed was Philips' only documentation on this issue. Philips' representatives informed the FDA investigator that no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time based on this occurrence in ^{(b) (4)} and no preventative maintenance procedure was implemented



other than the procedure implemented by Philips (b) (4) Ltd. in (b) (4) . Philips’ representatives explained to FDA that no action was taken by Philips in 2015 because Philips believed the implementation of the preventative maintenance procedure by Philips (b) (4) Ltd. in (b) (4) reflected cultural differences regarding response to complaints. However, FDA’s inspection identified no investigation by Philips to confirm this assumption.

Also in 2015, Philips contacted its supplier of the PE-PUR foam, (b) (4) (b) (4) , to inquire about the potential for degradation of the PE-PUR foam, based on information that Philips had received from a customer describing such degradation. In August 2016, (b) (4) relayed its supplier’s view to Philips: (b) (4)

” Despite this information, Philips took no corrective or preventive action with respect to the recalled devices at that time. In response to this inspection observation, Philips informed FDA that this correspondence with (b) (4) was related to Philips’ receipt of two complaints in 2015 “alleging an issue associated with the PE-PUR foam within the Trilogy devices,” and that in addition to contacting (b) (4) , Philips tested the foam material.¹⁵ Philips stated that the results of this testing were analyzed as part of a complaint investigation, which concluded that the risk management file addressed the hazard presented by the complaints, such that no escalation to a corrective and preventative action (CAPA) process was required.¹⁶ However, this testing spoke only to the limited finding that in the case of the (b) (4) foam samples “returned from service in a Pacific rim location,” spectroscopy results were “consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material.”¹⁷ In contrast, the communication from (b) (4) which Philips received approximately four months after these test results, described a potential risk of foam degradation in the presence of high temperature and humidity in as little time as a year. Philips provided no information to indicate that this communication was appropriately considered in Philips’ determination not to implement a formal CAPA at that time.

In addition, Philips’ own analysis of complaints confirmed to be related to foam degradation identified 110 such complaints received between 2014 and 2017.¹⁸ Testing conducted for Philips in 2016 also determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that “polyester urethanes show bad resistance against high humidity in

¹⁵ Letter from Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, Philips Respironics, Inc., to Office of Medical and Radiological Health Operations Division 1 – East, FDA, at 53 (Dec. 9, 2021).

¹⁶ *Id.*

¹⁷ (b) (4) (Apr. 1, 2016).

¹⁸ Letter from Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, Philips Respironics, Inc., to Office of Medical and Radiological Health Operations Division 1 – East, FDA, at 44 (Dec. 9, 2021).



combination with high temperature.”¹⁹ Other testing conducted for Philips in 2016 determined that, compared to PE-PUR foam, another type of foam, polyether urethane, “show[s] a far better resistance against high humidity at high temperature.”²⁰

Philips continued manufacturing products containing PE-PUR foam and did not take steps to initiate a corrective action until April 2018, with no formal CAPA initiated until June 2019. Instead, Philips’ actions in April 2018 involved the opening of a precursor to a CAPA (referred to by Philips as a “CAPA INV”), “to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken.”²¹ Philips closed this CAPA INV (CAPA INV 0988) two months later. CAPA INV 0988 led to implementation of a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure. Philips has since confirmed that under its current CAPA procedures, which were modified after CAPA INV 0988, “the cited issue would trigger a CAPA,” and this CAPA “would require that a verification of effectiveness check be performed.”²²

CAPA INV 0988 also failed to consider any devices other than the Trilogy 100 and 200 ventilators, despite Philips’ receipt of approximately 80 complaints related to foam degradation in CPAP and BiPAP devices containing PE-PUR foam between 2014 and 2017. Philips has confirmed that after CAPA INV 0988, Philips modified its CAPA procedures to include “requirements to help ensure that CAPAs are fully complete [and] appropriately scoped,” and that “processing the issue [that was the subject of INV 0988] through the current CAPA program would have result[ed] in an appropriate horizontal assessment.”²³

On December 12, 2018, several months after CAPA INV 0988 was closed, a report from additional testing conducted for Philips found that “[p]olyester polyurethane foam showed clear disintegration after 2 weeks of (b) (4) C (b) (4) %RH life test.”²⁴ More than six months later, following receipt of two complaints in April 2019 that sound abatement foam “is degrading and entering the air path,” Philips finally initiated a CAPA related to the issues associated with the PE-PUR foam in June 2019 (CAPA 7211). Even then, that CAPA failed to evaluate all relevant data. Philips’ search of FDA’s Manufacturer and User Facility Device Experience (MAUDE) database

¹⁹ Report AST282T-161438, Degradation of (b) (4) Respirionics Trilogy appliance, at 2 (Aug. 30, 2016).

²⁰ Report AST282T-161459, (b) (4) of (b) (4) foam, at 3 (Nov. 25, 2016).

²¹ Letter from Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, Philips Respironics, Inc., to Office of Medical and Radiological Health Operations Division 1 – East, FDA, at 40 (Dec. 9, 2021).

²² *Id.* Philips also has informed FDA that Philips is changing the complaint analysis procedures that were in place when Philips received complaints potentially related to foam degradation, stating that it will, among other things, “redesign its complaint-trending process and program so that [Philips] trends using a better statistical methodology at the complaint code level over time.” *Id.* at 47.

²³ Letter from Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, Philips Respironics, Inc., to Office of Medical and Radiological Health Operations Division 1 – East, FDA, at 42-43 (Dec. 9, 2021).

²⁴ Report AST282T-182160, (b) (4), at 4 (Dec. 12, 2018).



in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips’ analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988. In response to these findings, Philips has informed FDA that “[Philips] understands that it can enhance its methodology and process for better identifying relevant complaints when conducting a CAPA investigation.”²⁵

The quality system regulation (QSR) sets forth “[c]urrent good manufacturing practice” requirements, which constitute a set of “basic requirements applicable to manufacturers of finished medical devices” that are “intended to ensure that finished devices will be safe and effective and otherwise in compliance with” the FD&C Act.²⁶ As stated in the preamble to a final rule that amended the device current good manufacturing practice requirements in 1996, the QSR “provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.”²⁷ The QSR is thus central to device manufacturing, establishing a baseline set of current good manufacturing practices on top of which additional, particularized manufacturing practices are to be built.

Among the current good manufacturing practices set forth in the QSR, manufacturers must establish and maintain procedures for implementing corrective and preventative action, including “[a]nalyzing . . . complaints, returned product, and other sources of quality data to identify existing and potential causes” of quality problems; “[i]dentifying the action(s) needed to correct and prevent recurrence of . . . quality problems”; “[v]erifying and validating” the effectiveness of corrective and preventative action; and “[i]mplementing . . . changes in methods and procedures needed to correct and prevent identified quality problems.”²⁸ The preamble to the 1996 final rule emphasized that “it is essential that the manufacturer establish procedures for implementing corrective and preventative action,” and that “the concept of a total quality system which is a closed feedback loop system, and the practice of using that closed loop system in taking appropriate corrective and preventative action is paramount in ensuring that safe and effective

²⁵ Letter from Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, Philips Respironics, Inc., to Office of Medical and Radiological Health Operations Division 1 – East, FDA, at 49, 52 (Dec. 9, 2021).

²⁶ See 21 C.F.R. § 820.1.

²⁷ 61 Fed. Reg. 52602, 52603 (Oct. 7, 1996).

²⁸ 21 C.F.R. § 820.100.



medical devices are available to the public.”²⁹ Yet, since at least November 2015, Philips repeatedly failed to satisfy QSR requirements in connection with the manufacturing of the recalled devices.

In sum, the evidence indicates that, beginning as early as 2015, Philips failed to properly implement and maintain a quality system that included fundamental elements meant to ensure the safety and effectiveness of its devices, let alone a quality system that reflected state-of-the-art principles.

CDRH therefore believes, under the circumstances present here, there is sufficient evidence for FDA to determine that there are reasonable grounds to believe that since at least November 2015, Philips’ manufacturing of the recalled devices was not properly conducted with reference to the state of the art as it existed at the time that the devices were manufactured.

3. Although the use of ozone to clean the recalled devices might exacerbate degradation of the PE-PUR foam, the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care.

As documented by Philips in CAPA 7211, “based on the investigational analysis performed by (b) (4), Philips Respironics has reached the conclusion that the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity.”³⁰ Likewise, Philips states that “[t]he investigation determined the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions.”³¹ Although the CAPA also notes that degradation of the PE-PUR foam is “potentially caused and/or exacerbated by ... [u]se of unapproved cleaning and disinfection methods with [the affected devices] (e.g., ozone),”³² it further reports that “[f]oam degradation has ... been reported even when [o]zone disinfection was not reported.”³³ In addition, multiple tests conducted by or for Philips since at least August 2016 have identified degradation of PE-PUR foam in the absence of ozone cleaning agents and consistent with (b) (4) degradation of the PE-PUR foam.³⁴ Published literature likewise

²⁹ 61 Fed. Reg. at 52633, 52653.

³⁰ CAPA Detailed Report, PR ID: 7211, at 10.

³¹ *Id.* at 3.

³² *Id.* at 48, 68, 86.

³³ *Id.* at 3.

³⁴ See, e.g., Report AST282T-161438, Degradation of (b) (4) Respironics Trilogy appliance, at 2 (Aug. 30, 2016); Report AST282T-182160, (b) (4) (Dec. 12, 2018).

describes the susceptibility of PE-PUR foam to degrade under relatively mild environmental conditions, without the involvement of ozone.^{35, 36}

Even if the degradation of the PE-PUR foam was caused by the use of ozone cleaning agents, CDRH does not believe that the use of such agents constituted a failure to exercise due care. Only a subset of the devices affected by the recall included statements in their user manuals cautioning that the use of cleaning methods other than those recommended by Philips might affect product performance, and these statements gave no indication of the potential nature or severity of the possible effects. While the user manuals for certain other devices stated that only particular cleaning methods should be used, they did not warn of potential safety or performance impacts of using cleaning methods other than those specified. Nor did the labeling for any of the affected devices warn against the use of ozone cleaners in particular. Moreover, although FDA issued a safety communication in February 2020 stating that the safety and effectiveness of using ozone to clean CPAP machines had not been evaluated by the Agency, and warning of risks associated with using ozone for this purpose, the safety communication addressed risks wholly unrelated to the potential degradation of sound abatement foam. These risks focused on the potential for ozone gas leaks, or the temporary build-up of ozone, and did not describe any negative effects of ozone cleaners on the safety or efficacy of CPAP devices themselves. The safety communication also suggested that these risks applied when a space was not well ventilated, or if fresh air was not allowed to circulate through the device after cleaning. The safety communication thus did not give device users reason to anticipate that the use of ozone cleaners might significantly impact the safety of the devices themselves, or that the use of ozone cleaners in ventilated spaces (and utilizing procedures that permitted the circulation of fresh air through the devices) would necessarily present significant risks.

In addition, FDA’s safety communication regarding the use of ozone to clean CPAP machines was not issued until February 2020, approximately ten (10) months after Philips opened CAPA 7211. Even if the use of ozone to clean the recalled devices might have constituted a failure to exercise due care following FDA’s issuance of the safety communication, Philips’ own analysis identified hundreds of complaints confirmed to be related to foam degradation across affected products that were received between 2014 and 2019, before the safety communication was issued.

³⁵ See, e.g., H. Ulrich, *Polyurethane Stabilizers*, 18 J. Elastomers & Plastics 147, 149 (1986) (“polyester based polyurethanes undergo hydrolytic degradation in the presence of atmospheric moisture or water”); M. Szycher, Szycher’s Handbook of Polyurethanes 3-22 (1st ed. 1999) (“Water absorption and hydrolysis, especially at higher temperature, cause aging problems in polyurethane, particularly polyester urethane”).

³⁶ E-mail correspondence sent from Philips’ supplier of the PE-PUR foam (b) (4) to Philips in August 2016 also relayed the following view of (b) (4) supplier: (b) (4)

(b) (4) E-mail from (b) (4), to Richard Alfieri, Senior Staff Mechanical Engineer, Philips Respironics (Aug. 5, 2016).

For all of these reasons, the unreasonable risk presented by the recalled devices was not caused by a failure to exercise due care in the installation, maintenance, repair, or use of the devices related to the use of ozone cleaning agents. Moreover, FDA is not aware of any information unrelated to the use of ozone which may suggest that the unreasonable risk associated with the recalled devices was caused by a failure to exercise due care in the installation, maintenance, repair, or use of the devices by anyone other than Philips. Therefore, CDRH believes that there is sufficient evidence for FDA to determine that there are reasonable grounds to believe that the unreasonable risk associated with the recalled devices was not caused by the failure of a person other than the manufacturer, importer, distributor, or retailer of the devices to exercise due care in device installation, maintenance, repair, or use.

4. Patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices, therefore repairing, replacing and/or issuing a refund for the affected devices is necessary.

Even when patients and providers are aware of the unreasonable risk associated with the recalled devices, they cannot readily mitigate that risk. Efforts to remove the sound abatement foam from affected CPAP or BiPAP devices may present significant risks, as may the use of additional filters with such devices, and FDA has cautioned against such efforts. Although lifestyle changes may ultimately resolve the need for a CPAP or BiPAP device for some patients, the benefits of such changes would be experienced gradually and incompletely, and the use of a device would likely still be required. With respect to affected ventilators, the use of inline bacterial filters may potentially help to filter pieces of foam, yet such filters do not address potential chemical emissions, and they may impair the operation of the device due to increased air flow resistance. In addition, while patients may seek to avoid conditions that might facilitate degradation of the PE-PUR foam on a going-forward basis, doing so will not eliminate the risk from foam that has already undergone degradation, nor can such actions ensure that degradation or VOC emissions will not occur in the future.

Forgoing use of the affected devices may also pose significant risks. The recalled devices include several ventilators the use of which may be necessary to sustain life. In addition, both Philips and FDA recommend that patients consult with healthcare providers to decide whether to stop using affected CPAP or BiPAP machines.³⁷ A provider may determine that despite the substantial risk associated with use of the recalled devices, the benefits to the patient of continued treatment with the device may be too critical to forgo. Even when patients are advised to stop use of a recalled device, the risks of forgoing treatment may be substantial.

³⁷ See FDA, Update: Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication, <https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health> (last updated Mar. 14, 2022); Philips, Medical Device Recall Information, <https://www.usa.philips.com/healthcare/e/sleep/communications/src-update>.



In light of the inability of patients and providers to readily mitigate the unreasonable risk associated with the recalled devices, the notification ordered under section 518(a) of the FD&C Act on March 10, 2022 is not sufficient to eliminate the risk, and repairing, replacing, and/or issuing a refund for the affected devices is necessary. Although notification as ordered under section 518(a) may be *necessary* to eliminate the risk, such notification cannot eliminate the risk by itself. Patients and providers who are informed of the risk associated with the recalled devices cannot be expected to resolve that risk on their own, nor can all patients be expected to stop using the affected products without potentially exposing themselves to further risks. Rather, for patients in need of a ventilator or a CPAP or BiPAP machine, elimination of the risk associated with the recalled devices requires fixing the affected products, or otherwise utilizing substitute products, whether provided by Philips or by another manufacturer. CDRH therefore believes that there is sufficient evidence for FDA to determine that the section 518(a) notification issued on March 10, 2022 alone is not sufficient to eliminate the unreasonable risk associated with the recalled devices, and that elimination of the risk requires repairing the devices, replacing the devices, and/or issuing a refund that may facilitate access to alternate devices.

Conclusion

For the reasons described above, CDRH believes that there is sufficient evidence for FDA to determine that the criteria in section 518(b)(1)(A)(i)-(iv) have been met to issue an order under section 518(b) requiring Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of the recalled devices that were manufactured after November 2015. This letter reflects CDRH's tentative view, based on the information presently available, and does not reflect a final determination by CDRH or FDA on any issue discussed herein.

Pursuant to section 518(b)(1)(B), if an order is issued requiring Philips to submit such a plan, FDA may decline to approve the plan submitted under section 518(b) if FDA determines, after affording an opportunity for an informal hearing, that the action(s) to be taken under the plan, or the manner in which such action(s) are to be taken under the plan, will not assure that the unreasonable risk of substantial harm to the public health associated with the affected devices will be eliminated. Based on the status of Philips' recall as of the date of this letter, CDRH believes that, if an order were to be issued to Philips under section 518(b), the plan submitted by Philips in response to that order should provide for significant improvements to Philips' ongoing repair and replacement activities to speed the pace of remediation and address other deficiencies identified by CDRH and communicated to Philips, to the extent such improvements are achievable by Philips. CDRH further believes that, if an order were to be issued to Philips under section 518(b), Philips should consider proposing a plan that provides for the issuance of refunds as described in section 518(b)(2)(C).



Under section 518(b), Philips is afforded an opportunity for an informal hearing before FDA determines whether the criteria for issuing an order have been met. If you choose to request an informal hearing, your request for a hearing must be received by FDA in writing no later than seven (7) calendar days after the date of this letter. If no response is received by FDA within this time, the opportunity for a hearing will be deemed to have been refused and no hearing will be held (see 21 C.F.R. § 16.22(b)).

Your request for a hearing should be directed to:

CDRH-Ombudsman
Center for Devices and Radiological Health
U.S. Food and Drug Administration
E-mail address: CDRHombudsman@fda.hhs.gov
cc: Matthew.Warren@fda.hhs.gov

If Philips files a timely request for a hearing, the company must, within 30 days of receipt of this letter, submit information to demonstrate that there is genuine and substantial issue of material fact that requires a hearing. Pursuant to 21 C.F.R. § 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or the Commissioner's delegate determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law.

Alternatively, if Philips does not desire a hearing but wishes to submit a written response, the company may so notify the agency within seven (7) calendar days of the date of this letter, and then submit a written response within 30 calendar days of this letter. The response should include any information that Philips believes is relevant to whether an order should be issued under section 518(b) of the FD&C Act. Under this approach, FDA will make its final decision regarding whether to issue an order under section 518(b) on the bases explained in this letter, any written response from the company, and other information available to FDA.

Please be aware that this letter, and any response from the company to this letter, may be posted on FDA's website, with redactions for any confidential information.

If you have any questions regarding this letter, please contact Denise Hampton at Denise.Hampton@fda.hhs.gov.



Sincerely,

Malvina Eydelman, M.D.

Director

OHT 1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

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additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise.

§ 15.30 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or a designee may preside at the hearing, except where a regulation provides that the Commissioner will preside personally. The presiding officer may be accompanied by other FDA employees or other Federal Government employees designated by the Commissioner, who may serve as a panel in conducting the hearing.

(b) The hearing will be transcribed.

(c) Persons may use their allotted time in whatever way they wish, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 15.25. The presiding officer may allot additional time to any person when the officer concludes that it is in the public interest, but may not reduce the time allotted for any person without the consent of the person.

(d) If a person is not present at the time specified for the presentation, the persons following will appear in order, with adjustments for those appearing at their scheduled time. An attempt will be made to hear any person who is late at the conclusion of the hearing. Other interested persons attending the hearing who did not request an opportunity to make an oral presentation will be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

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(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

(a) The administrative record of a public hearing before the Commissioner consists of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions under § 15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding will be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Sec.

16.1 Scope.

16.5 Inapplicability and limited applicability.

Subpart B—Initiation of Proceedings

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Subpart C—Commissioner and Presiding Officer

- 16.40 Commissioner.
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- 16.44 Communication to presiding officer and Commissioner.

Subpart D—Procedures for Regulatory Hearing

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- 16.80 Administrative record of a regulatory hearing.
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- 16.119 Reconsideration and stay of action.

Subpart G—Judicial Review

- 16.120 Judicial review.

AUTHORITY: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

SOURCE: 44 FR 22367, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no pro-

cedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices and drugs (see §§ 800.55(g) and 1.980(g) of this chapter).
Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k of this chapter).

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 (see part 112, subpart P of this chapter).

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(e)(3) of the act relating to the temporary suspension of approval of a premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516(b) of the act regarding a proposed regulation to ban a medical device with a special effective date.

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 518(e) of the act relating to a cease distribution and notification order or mandatory recall order concerning a medical device for human use.

Section 520(f)(2)(D) of the act relating to exemptions or variances from device current good manufacturing practice requirements (see § 820.1(d)).

Section 520(g)(4) and (g)(5) of the act relating to disapproval and withdrawal of approval of an application from an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c) of this chapter).

Section 903(a)(8)(B)(ii) of the Federal Food, Drug, and Cosmetic Act relating to the misbranding of tobacco products.

Section 906(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act relating to the establishment of good manufacturing practice requirements for tobacco products.

Section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a new tobacco product to be introduced or delivered for introduction into interstate commerce.

Section 911(j) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of

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an order allowing a modified risk tobacco product to be introduced or delivered for introduction into interstate commerce.

(2) Regulatory provisions:

§§1.634 and 1.664, relating to revocation of recognition of an accreditation body and withdrawal of accreditation of third-party certification bodies that conduct food safety audits of eligible entities in the food import supply chain and issue food and facility certifications.

§ 56.121(a), relating to disqualifying an institutional review board or an institution.

§ 58.204(b), relating to disqualifying a testing facility.

§ 71.37(a), relating to use of food containing a color additive.

§ 80.31(b), relating to refusal to certify a batch of a color additive.

§ 80.34(b), relating to suspension of certification service for a color additive.

§ 99.401(c), relating to a due diligence determination concerning the conduct of studies necessary for a supplemental application for a new use of a drug or device.

§§112.201 through 112.213, (see part 112, subpart R of this chapter), relating to withdrawal of a qualified exemption.

§§117.251 through 117.287 (part 117, subpart E of this chapter), relating to withdrawal of a qualified facility exemption.

§ 130.17(1), relating to a temporary permit to vary from a food standard.

§ 170.17(b), relating to use of food containing an investigational food additive.

§ 202.1(j)(5), relating to approval of prescription drug advertisements.

§ 312.70, relating to whether an investigator is eligible to receive test articles under part 312 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

§ 312.70(d) and 312.44, relating to termination of an IND for a sponsor.

§ 312.160(b), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

§§507.60 through 507.85 (part 507, subpart D of this chapter) relating to withdrawal of a qualified facility exemption.

§ 511.1(b)(5), relating to use of food containing an investigational new animal drug.

§ 511.1 (c)(1), relating to whether an investigator is eligible to receive test articles under part 511 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices,

new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

§ 511.1(c) (4) and (d), relating to termination of an INAD for a sponsor.

§ 812.119, relating to whether an investigator is eligible to receive test articles under part 812 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

§ 814.46(c) relating to withdrawal of approval of a device premarket approval application.

§ 822.7(a)(3), relating to an order to conduct postmarket surveillance of a medical device under section 522 of the act.

§ 830.130, relating to suspension or revocation of the accreditation of an issuing agency.

§ 895.30(c), regarding a proposed regulation to ban a medical device with a special effective date.

§ 900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.

§ 900.14, relating to suspension or revocation of a mammography certificate.

§ 900.25, relating to approval or withdrawal of approval of certification agencies.

§ 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

§ 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.

§ 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.

§ 1107.1(d), relating to rescission of an exemption from the requirement of demonstrating substantial equivalence for a tobacco product.

§ 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

§ 1270.43(e), relating to the retention, recall, and destruction of human tissue.

§ 1271.440(e) relating to the retention, recall, and destruction of human cells, tissues, and cellular and tissue-based products

(HCT/Ps), and/or the cessation of manufacturing HCT/Ps.

[44 FR 22367, Apr. 13, 1979]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §16.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and §1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act and §1.94, or of an electronic product under section 360(a) of the Public Health Service Act and §1005.20.

(3) Factory inspections, recalls (except mandatory recalls of medical devices intended for human use), regulatory letters, and similar compliance activities related to law enforcement.

(4) A hearing on an order for re-labeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and §§101.17(h) and 115.50 of this chapter.

(5) A hearing on an order for diversion or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), and §118.12 of this chapter.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in subpart A of part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

[44 FR 22367, Apr. 13, 1979, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 76110, Dec. 5, 2000; 74 FR 33095, July 9, 2009]

Subpart B—Initiation of Proceedings

§ 16.22 Initiation of regulatory hearing.

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the FDA employee to whom any request for hearing is to be addressed.

(5) Refer to FDA's guideline on electronic media coverage of its administrative proceedings (21 CFR part 10, subpart C).

(b) A person offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 3 working days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated FDA employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Commissioner will designate a presiding officer, and the hearing will take place at a time and location agreed upon by the party requesting the hearing, the FDA, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section will not operate to delay or stay any administrative action, including enforcement action by the agency unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

[44 FR 22367, Apr. 13, 1979, as amended at 49 FR 32173, Aug. 13, 1984]

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§ 16.24 Regulatory hearing required by the act or a regulation.

(a) A regulatory hearing required by the act or a regulation under §16.1(b) will be initiated in the same manner as other regulatory hearings subject to the additional procedures in this section.

(b) [Reserved]

(c) The notice will state whether any action concerning the matter that is the subject of the opportunity for hearing is or is not being taken pending the hearing under paragraph (d) of this section.

(d) The Commissioner may take such action pending a hearing under this section as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis.

(e) The hearing may not be required to be held at a time less than 2 working days after receipt of the request for hearing.

(f) Before the hearing, FDA will give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by FDA at the hearing in support of the decision or action. This information may be given orally or in writing, in the discretion of FDA.

(g) FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy will also be provided in advance if the other participant could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of

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the hearing to make a submission concerning the article or information.

[44 FR 22367, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982; 54 FR 9037, Mar. 3, 1989]

§ 16.26 Denial of hearing and summary decision.

(a) A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom authority is delegated to make the final decision on the matter determines that no genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(b) After a hearing commences, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. For the purpose of this paragraph, a hearing commences upon the receipt by FDA of a request for hearing submitted under §16.22(b).

(c) The Commissioner or his or her delegate may review any summary decision of the presiding officer issued under paragraph (b) of this section at the request of a party or on the Commissioner's or his or her delegate's own initiative.

[53 FR 4615, Feb. 17, 1988, as amended at 69 FR 17290, Apr. 2, 2004]

Subpart C—Commissioner and Presiding Officer

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority on a matter for which a regulatory hearing is available under this part, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a center director.

[69 FR 17290, Apr. 2, 2004]

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, or, consistent with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a center director, the presiding officer may be an official in another center or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted, as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989; 67 FR 53306, Aug. 15, 2002]

§ 16.44 Communication to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding officer or the Commissioner, e.g., a response by the presiding officer to a request for a change in the time of the hearing, is to be sent to all participants by the person writing the letter or the memorandum.

Subpart D—Procedures for Regulatory Hearing**§ 16.60 Hearing procedure.**

(a) A regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure under § 20.61; or to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure under § 20.64.

(1) The Commissioner may determine that a regulatory hearing is closed either on the Commissioner's initiative or on a request by the party asking for a regulatory hearing, in the request for the hearing.

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(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in §20.81(a) and FDA representatives with a direct professional interest in the subject matter of the proceeding are entitled to attend.

(b) A regulatory hearing will be conducted by a presiding officer. Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing may then present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision,

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with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under §10.19 to suspend, modify, or waive any provision of this part.

[44 FR 22367, Apr. 13, 1979, as amended at 66 FR 6469, Jan. 22, 2001; 66 FR 12850, Mar. 1, 2001]

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and comments on the report under §16.60(e).

(5) All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in §16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

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§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under § 16.1(a), the Commissioner shall consider the administrative record of the hearing specified in § 16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

(1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regu-

latory action which is the subject of a hearing under this part

PART 17—CIVIL MONEY PENALTIES HEARINGS

Sec.

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- 17.2 Maximum penalty amounts.
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AUTHORITY: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa-28; 5 U.S.C. 554, 555, 556, 557.

SOURCE: 60 FR 38626, July 27, 1995, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 17 appear at 68 FR 24879, May 9, 2003.

§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that authorize civil money penalties that are governed by these procedures.

(a) Section 303(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act

§ 10.200

(3) As discussed in paragraph (f)(3) of this section, you may at any time suggest that FDA revise a guidance document.

(1) *How will FDA ensure that FDA staff are following GGP's?* (1) All current and new FDA employees involved in the development, issuance, or application of guidance documents will be trained regarding the agency's GGP's.

(2) FDA centers and offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed.

(m) *How can you get copies of FDA's guidance documents?* FDA will make copies available in hard copy and, as feasible, through the Internet.

(n) *How will FDA keep you informed of the guidance documents that are available?* (1) FDA will maintain on the Internet a current list of all guidance documents. New documents will be added to this list within 30 days of issuance.

(2) Once a year, FDA will publish in the FEDERAL REGISTER its comprehensive list of guidance documents. The comprehensive list will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list.

(3) FDA's guidance document lists will include the name of the guidance document, issuance and revision dates, and information on how to obtain copies of the document.

(o) *What can you do if you believe that someone at FDA is not following these GGP's?* If you believe that someone at FDA did not follow the procedures in this section or that someone at FDA treated a guidance document as a binding requirement, you should contact that person's supervisor in the center or office that issued the guidance document. If the issue cannot be resolved, you should contact the next highest supervisor. You can also contact the center or office ombudsman for assistance in resolving the issue. If you are unable to resolve the issue at the center or office level or if you feel that you are not making progress by going through the chain of command, you may ask the Office of the Chief Mediator and Ombudsman to become involved.

[65 FR 56477, Sept. 19, 2000, as amended at 83 FR 13416, Mar. 29, 2018]

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Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

SOURCE: 49 FR 14726, Apr. 13, 1984, unless otherwise noted.

§ 10.200 Scope.

This guideline describes FDA's policy and procedures applicable to electronic media coverage of agency public administrative proceedings. It is a guideline intended to clarify and explain FDA's policy on the presence and operation of electronic recording equipment at such proceedings and to assure uniform and consistent application of practices and procedures throughout the agency.

§ 10.203 Definitions.

(a) *Public administrative proceeding* as used in this guideline means any FDA proceeding which the public has a right to attend. This includes a formal evidentiary public hearing as set forth in part 12, a public hearing before a Public Board of Inquiry as set forth in part 13, a public hearing before a Public Advisory Committee as set forth in part 14, a public hearing before the Commissioner as set forth in part 15, a regulatory hearing before FDA as set forth in part 16, consumer exchange meetings, and Commissioner's public meetings with health professionals.

(b) *Advance notice* as used in this guideline means written or telephone notification to FDA's Office of Public Affairs (Press Relations Staff) of intent to electronically record an agency public administrative proceeding.

(c) *Electronic recording* as used in this guideline means any visual or audio recording made by videotape recording equipment or moving film camera, and/or other electronic recording equipment.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

§ 10.204 General.

(a) FDA has for many years willingly committed itself to a policy of openness. In many instances FDA has sought to make the open portions of

agency public administrative proceedings more accessible to public participation. Similarly, FDA has sought, wherever possible, to allow full written media access to its proceedings, so that members of the press would have the opportunity to provide first-hand reports. However, because electronic media coverage presents certain difficulties that are easier to resolve with advance notice to the agency and all participants, FDA believes that codification of its policy will facilitate and further increase media access to its public administrative proceedings. The agency intends to refer to this guideline when notices of hearing, or individual advisory committee meetings, are published in the FEDERAL REGISTER. Thus, all parties to a proceeding will be on notice that the proceeding may be recorded electronically and any person interested in videotaping or otherwise recording the proceeding will be notified that there are established procedures to be followed.

(b) The designated presiding officer of a public administrative proceeding retains the existing discretionary authority set forth in specific regulations pertaining to each type of administrative proceeding to regulate the conduct of the proceeding over which he or she presides. The responsibilities of the presiding officer, established elsewhere in parts 10 through 16, include an obligation to be concerned with the timely conduct of a hearing, the limited availability of certain witnesses, and reducing disruptions to the proceeding which may occur. Each proceeding varies, and the presiding officer cannot anticipate all that might occur. Discretionary authority to regulate conduct at a proceeding has traditionally been granted to presiding officers to enable them to fulfill their responsibility to maintain a fair and orderly hearing conducted in an expeditious manner.

(c) This guideline provides the presiding officer with a degree of flexibility in that it sets forth the agency's policy as well as the procedures that presiding officers should ordinarily follow, but from which they may depart in particular situations if necessary, subject to the presumption of openness of public proceedings to electronic media coverage. The presiding officer's

discretion to establish additional procedures or to limit electronic coverage is to be exercised only in the unusual circumstances defined in this guideline. Even though a presiding officer may establish additional procedures or limits as may be required in a particular situation, he or she will be guided by the policy expressed in this guideline in establishing these conditions. The presiding officer may also be less restrictive, taking into account such factors as the duration of a hearing and the design of the room.

(d) If a portion or all of a proceeding is closed to the public because material is to be discussed that is not disclosable to the public under applicable laws, the proceeding also will be closed to electronic media coverage.

(e) The agency requests advance notice of intent to record a proceeding electronically to facilitate the orderly conduct of the proceeding. Knowledge of anticipated media coverage will allow the presiding officer to make any special arrangements required by the circumstances of the proceeding. The agency believes that this guideline establishes sufficiently specific criteria to promote uniformity.

(f) The agency would like to allow all interested media representatives to videotape a proceeding in which they have an interest. However, should space limitations preclude a multitude of cameras, the presiding officer may require pool sharing. In such a case, pool sharing arrangements of the resulting videotape should be made between those allowed to film and those who were excluded. Arrangements for who is designated to present the pool and a method of distributing the resulting film or tape may be determined by the established networks' pooling system. However, the agency has a strong commitment to ensuring that media representatives other than the major networks also be able to obtain a copy of the tape at cost. FDA is concerned that if the network pool representative wishes to record only a short portion of a proceeding, but an excluded party wishes to record the entire proceeding, confusion will result. The agency expects the interested media representatives to negotiate a suitable agreement among themselves

before commencement of the proceeding. For example, the network pool representatives might agree to record a portion of the proceeding up to a break in the proceeding, at which time, while the network representative is disassembling equipment, another media representative might set up to continue recording. If an agreement cannot be reached before the proceeding, the agency will use the time of receipt of any advance notice to determine the representation for each category of media, e.g., one network reporter, one independent reporter. The agency recommends that parties intending to videotape provide as much advance notice as possible, so that the agency may best respond to the needs of the electronic media.

(g) To ensure the timely conduct of agency hearings and to prevent disruptions, equipment is to be stationary during a proceeding and should be set up and taken down when the proceeding is not in progress. As noted previously, the presiding officer may, at his or her discretion, be less restrictive if appropriate.

(h) The agency recognizes that electronic media representatives may desire only short footage of a proceeding, a facsimile of the proceeding, and/or interview opportunities and may be unnecessarily restricted by requirements for setting up before a proceeding and then waiting until a break in the proceeding before being permitted to take down their equipment. To accommodate this possibility, FDA's Press Relations Staff will attempt to make arrangements to respond to such needs by, for example, requesting that the presiding officer provide a break shortly after commencement of the proceeding to permit take down of equipment.

(i) The agency is making a full commitment to allowing, whenever possible, electronic coverage of its public administrative proceedings subject to the limited restrictions established in this guideline.

§ 10.205 Electronic media coverage of public administrative proceedings.

(a) A person may record electronically any open public administrative proceeding, subject to the procedures

specified in this guideline. The procedures include a presumption that agency public proceedings are open to the electronic media. Whenever possible, FDA will permit all interested persons access to record agency public administrative proceedings. Restrictions other than those listed in § 10.206 will be imposed only under exceptional circumstances.

(b) A videotape recording of an FDA public administrative proceeding is not an official record of the proceeding. The only official record is the written transcript of the proceeding, which is taken by the official reporter.

§ 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

(a) To facilitate the agency's response to media needs, a person intending to videotape an FDA public administrative proceeding should, whenever possible, provide advance notice to the Press Relations Staff (HFI-20), Office of Public Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, in writing or by telephone (telephone 301-443-4177), at least 48 hours in advance of the proceeding. The Press Relations Staff will inform the presiding officer that the proceeding will be attended by representatives of the electronic media, and ascertain whether any special provisions in addition to those set forth in this subpart are required by the presiding officer. If so, the Press Relations Staff will function as a liaison between the presiding officer and the person intending to record the proceeding in facilitating any procedures in addition to those outlined in this subpart. The presiding officer will not deny access for failure to provide a 48-hour advance notice. Any advance notice may describe the intended length of recording if known, the amount and type of equipment to be used, and any special needs such as interviews.

(b) Cameras should be completely set up before a proceeding is scheduled to begin or during a break in the proceeding and should remain standing in the area designated for electronic media equipment. Cameras may be taken down only during breaks or after the hearing is over. Roving cameras

will not be permitted during the proceeding. Any artificial lighting should be unobtrusive. Microphones, like cameras, should be in place before the start of a proceeding and may be taken down as indicated in this paragraph.

(c) When space in the hearing room is limited, the presiding officer may restrict the number of cameras or the equipment present. Should such a restriction become necessary, the pool arrangements are the responsibility of the participating media. The agency encourages the network pool to make copies of the tape, film, or other product available at cost to nonpool participants. However, if this is not possible, the agency may need to use the time of receipt of any advance notice to determine the representation for each category, e.g., one network reporter, one independent reporter, etc.

(d) *Off the record* portions of a proceeding may not be videotaped.

(e) Before or during the proceeding, the presiding officer may establish other conditions specific to the proceeding for which the request is being made. These conditions may be more or less restrictive than those stated in this guideline, except that the presiding officer shall observe the agency's presumption of openness of its public proceedings to the electronic media. Only a substantial and clear threat to the agency's interests in order, fairness, and timeliness authorizes the presiding officer to impose additional restrictions. This threat must outweigh the public interest in electronic media coverage of agency proceedings. Additional restrictions shall be narrowly drawn to the particular circumstances. The following factors are listed to assist presiding officers in determining whether the agency's interest is sufficiently compelling to call for the unusual step of imposing additional restrictions. Generally this step is justified when one of the following factors is met:

(1) Electronic recording would result in a substantial likelihood of disruption that clearly cannot be contained by the procedures established in paragraphs (a) through (d) of this section.

(2) Electronic recording would result in a substantial likelihood of prejudicial impact on the fairness of the pro-

ceeding or the substantive discussion in a proceeding.

(3) There is a substantial likelihood that a witness' ability to testify may be impaired due to unique personal circumstances such as the age or psychological state of the witness or the particularly personal or private nature of the witness' testimony, if the witness' testimony were electronically recorded.

(f) Before the proceeding, the Press Relations Staff will, upon request, provide written copies of any additional conditions imposed by the presiding officer (as described in paragraph (e) of this section) to requesting members of the media. Any appeals should be made in accordance with paragraph (h) of this section.

(g) The presiding officer retains authority to restrict or discontinue videotaping or other recording of a proceeding, or parts of a proceeding, should such a decision become necessary. The presiding officer's responsibility to conduct the hearing includes the right and duty to remove a source of substantial disruption. In exercising his or her authority, the presiding officer shall observe the presumption that agency public proceedings are open to the electronic media. The presiding officer shall exercise his or her discretion to restrict or discontinue electronic coverage of a public proceeding, or portions of a public proceeding, only if he or she determines that the agency's interest in the fair and orderly administrative process is substantially threatened. A clear and substantial threat to the integrity of agency proceedings must clearly outweigh the public interest in electronic media coverage of the proceedings before additional restrictions are imposed on the electronic media during the course of the proceedings. The factors noted in paragraph (e) of this section indicate the kind of substantial threat to the agency interests that may require imposing additional restrictions during the course of the proceedings. If additional requirements are established during the hearing, the presiding officer shall notify immediately the Deputy Commissioner of Food and Drugs of that fact by telephone and submit a written explanation of the circumstances that

necessitated such an action within 24 hours or sooner if requested by the Deputy Commissioner. In the absence or unavailability of the Deputy Commissioner, the presiding officer shall notify the Associate Commissioner for Regulatory Affairs.

(h) A decision by a presiding officer, made either before the proceeding or during the course of a proceeding, to establish requirements in addition to the minimum standards set forth in this guideline may be appealed by any adversely affected person who intends to record the proceeding electronically. Appeals may be made in writing or by phone to the Deputy Commissioner or, in his or her absence, to the Associate Commissioner for Regulatory Affairs. The filing of an appeal, whether before or during a proceeding, does not require the presiding officer to interrupt the proceeding. However, the Deputy Commissioner or, in his or her absence, the Associate Commissioner for Regulatory Affairs will resolve an appeal as expeditiously as possible so as to preserve, to the extent possible, the reporters' opportunity to record the proceedings.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

Subpart A—General Provisions

Sec.

- 11.1 Scope.
- 11.2 Implementation.
- 11.3 Definitions.

Subpart B—Electronic Records

- 11.10 Controls for closed systems.
- 11.30 Controls for open systems.
- 11.50 Signature manifestations.
- 11.70 Signature/record linking.

Subpart C—Electronic Signatures

- 11.100 General requirements.
- 11.200 Electronic signature components and controls.
- 11.300 Controls for identification codes/passwords.

AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 262.

SOURCE: 62 FR 13464, Mar. 20, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 11.1 Scope.

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with § 11.2, unless paper records are specifically required.

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.