



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1106]

Alcohol-Based Hand Sanitizer Products; Withdrawal of Three Temporary Guidance Documents Issued During the Public Health Emergency of the Coronavirus Disease 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of three guidance documents entitled “Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19),” “Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency,” and “Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19),” which were issued in March 2020 (and updated March 27, 2020, April 15, 2020, June 1, 2020, August 7, 2020, and February 10, 2021). FDA is withdrawing these three guidance documents because current data indicate that consumers and healthcare personnel are no longer experiencing difficulties accessing alcohol-based hand sanitizer products, and these temporary policies are no longer needed to help meet demand for alcohol-based hand sanitizer products or for alcohol for use in alcohol-based hand sanitizer.

DATES: The withdrawal date for the three guidances is December 31, 2021. Firms manufacturing alcohol under the temporary policies for use in alcohol-based hand sanitizers and firms preparing alcohol-based hand sanitizers under the temporary policies must cease production of these products by December 31, 2021. Firms must cease, by March 31, 2022, distribution of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. After March 31, 2022, FDA intends to cease its

temporary policy of not taking action with regard to distribution of hand sanitizers, or alcohol for use in alcohol-based hand sanitizers, prepared consistent with the circumstances described in the guidance documents.

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SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA’s commitment to providing timely guidance to support continuity and response efforts to the Coronavirus Disease 2019 (COVID-19)¹ pandemic, in March 2020, the Agency published three guidance documents to provide regulatory flexibility to certain firms to help meet the demand for alcohol-based hand sanitizer during the COVID-19 public health emergency (PHE).² The guidance documents communicate the Agency’s temporary policies on the manufacture of alcohol for use in alcohol-based hand sanitizers, or alcohol-based hand sanitizers for consumer use and for use as healthcare personnel hand rubs³ for the duration of the PHE declared by the Secretary of Health and Human Services on January 31, 2020, and subsequently renewed. The following is a brief description of each guidance:

- The first guidance⁴, “Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19),” communicates

¹ The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19).

² For example, as explained in the guidance entitled “Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19),” provided that circumstances described in the guidance are present, FDA does not intend to take action against firms, for the duration of the public health emergency, for violations of sections 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)) or sections 501(a)(2)(B), 502(f)(1), 505, or 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B), 352(f)(1), 355, and 360eee-1), which include certain aspects of current good manufacturing practice, certain labeling requirements, new drug application requirements, and pharmaceutical distribution supply chain requirements.

³ FDA uses the term “hand sanitizer” throughout this Notice of Withdrawal, and the referenced guidance documents, to refer to OTC topical antiseptic rubs for use by consumers, as well as those for use by healthcare personnel in hospital and healthcare settings.

⁴ Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-during>.

FDA’s policy for the temporary preparation of certain alcohol-based hand sanitizer products by firms that register their establishment with FDA as a nonprescription over-the-counter (OTC) drug manufacturer, re-packager, or re-labeler, under the circumstances described in the guidance.

- The second guidance⁵, “Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency,” communicates FDA’s policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State- or territory-licensed pharmacies or Federal facilities and registered outsourcing facilities, under the circumstances described in the guidance.
- The third guidance⁶, “Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19),” communicates FDA’s policy for the temporary manufacture of alcohol (i.e., ethanol or ethyl alcohol) by firms for use as the active pharmaceutical ingredient in alcohol-based hand sanitizers under the circumstances described in the guidance.

We appreciate industry’s willingness to help supply hand sanitizer to the market in response to the COVID-19 PHE.

As explained in these guidance documents, FDA has continually assessed the needs and circumstances related to these temporary policies, and as relevant needs and circumstances evolved, FDA made updates and modifications to these temporary policies. The guidance documents also state that this assessment includes withdrawing these temporary policies as appropriate.

Based on our review of currently available data, we have determined that the needs and circumstances related to these temporary policies have evolved such that the temporary policies

⁵ Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health>.

⁶ Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-manufacture-alcohol-incorporation-alcohol-based-hand-sanitizer-products-during>.

are no longer needed and the three guidance documents should be withdrawn.⁷ As explained in this document, this determination is based on current data that show that demand for alcohol-based hand sanitizer has decreased and the supply of hand sanitizer from traditional manufacturers (i.e., firms other than those that entered into the OTC drug industry for the first time in order to supply hand sanitizers during the COVID-19 PHE) has increased. Most consumers and healthcare personnel are no longer experiencing difficulties accessing alcohol-based hand sanitizer products.

During the course of the COVID-19 PHE, FDA has conducted several surveys of hospital systems to monitor the supply and sources of alcohol-based hand sanitizer products. Based on the results of these surveys, current data show that the hand sanitizer supply disruption in hospitals has decreased significantly and that hand sanitizer from traditional manufacturers now comprise the majority of these hospital systems' supply. Specifically, all the hospital systems that responded to FDA's July 2021 survey on hand sanitizer supply stated that they are not experiencing a current disruption in their supply of hand sanitizer, and only 9 percent of these hospital systems anticipated a future disruption in supply. In addition, 94 percent of the hospital systems responding to the July 2021 survey reported that the majority of their current hand sanitizer product is produced by traditional manufacturers. Recent reports also indicate that there is now a surplus of hand sanitizer products on retail shelves.⁸ Moreover, certain traditional hand sanitizer manufacturers indicate that they are able to meet demand and fully supply the

⁷ We note that withdrawal of these guidance documents will not cause an assessment of fees on manufacturers of OTC hand sanitizers under the Over-the-Counter Monograph Drug User Fee Program (OMUFA). OMUFA fees are distinct from these guidance documents and are addressed in FDA's *Federal Register* notice of March 26, 2021 (86 FR 16223), entitled "Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021." As this *Federal Register* notice explains, "FDA will not assess OMUFA facility fees upon those firms that first registered with FDA on or after the January 27, 2020 declaration of the COVID-19 Public Health Emergency (PHE), solely for purposes of manufacturing hand sanitizer products during the PHE" (86 FR 16223 at 16225). Additional information is available in this FDA *Federal Register* notice and the Health and Human Services Federal Register notice of January 12, 2021 (86 FR 2420).

⁸ See, e.g., the newspaper articles at <https://www.wsj.com/articles/america-is-awash-in-hand-sanitizer-11621522829>; https://www.washingtonpost.com/local/last-year-hand-sanitizer-was-a-precious-commodity-now-theyre-giving-it-away/2021/06/24/351f1278-d504-11eb-9f29-e9e6c9e843c6_story.html; <https://www.usatoday.com/story/money/2021/04/08/hand-sanitizer-deals-donations-surplus-panic-buying-pandemic/7120815002/> (Refs. 1, 2, and 3).

marketplace with hand sanitizer products.⁹ A large manufacturer of hand sanitizer products has expanded production capacity and is producing and shipping 300 percent more hand sanitizer product than in 2019.¹⁰

FDA published its temporary policies for alcohol-based hand sanitizers in response to the increase in demand for alcohol-based hand sanitizer products during the COVID-19 PHE and with the understanding that some consumers and healthcare personnel were experiencing difficulties accessing alcohol-based hand sanitizer products. Although the PHE is still ongoing¹¹ and there currently is an increase in COVID-19 cases, the data indicate that: (1) supply from traditional manufacturers has increased; (2) the demand for alcohol-based hand sanitizer that existed earlier in the pandemic has significantly decreased; and (3) most consumers and healthcare personnel are no longer having difficulty accessing alcohol-based hand sanitizer products. Additionally, since declaration of the COVID-19 PHE,¹² some hand sanitizer products made by firms that entered the market during the COVID-19 PHE have been recalled, placed on import alert, and/or been the subject of compliance actions due to quality and other issues. Accordingly, the needs and circumstances related to these temporary policies have evolved such that the temporary policies are no longer warranted and the guidance documents should be withdrawn.

We note that the recently enacted Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136) added section 505G to the FD&C Act (21 U.S.C. 355g). Under section

⁹ See April 28, 2021, letter from the American Cleaning Institute/Consumer Healthcare Products Association to FDA, available at <https://www.regulations.gov/comment/FDA-2020-D-1106-0164> (Ref. 4) (stating that their members “have the capacity to fully supply the marketplace” and have “increased production of cGMP-compliant products to meet the demand for both consumer and healthcare markets,” at 3).

¹⁰ See <https://www.gojo.com/en/Newsroom/Press-Releases/2021/PURELL-Brand-Strongly-Positioned-to-Support-Safe-Reopening-of-Schools> (Ref. 5).

¹¹ Secretary of Health and Human Services, “Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus” (originally issued January 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx> (Ref. 6).

¹² The HHS Declaration of a Public Health Emergency is available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

505G(a)(3) of the FD&C Act, drugs that were classified as category III¹³ in a tentative final monograph (TFM) that is the most recently applicable proposal or determination for such drugs issued under 21 CFR part 330--and that were not classified in such a TFM as category II for safety or effectiveness--are not required to have an approved application under section 505 to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM and comply with all other applicable requirements. This includes topical antiseptic products marketed in conformity with the 1994 TFM for OTC topical antiseptics (59 FR 31402, June 17, 1994) as further amended by the 2016 Consumer Antiseptic Rub proposed rule (81 FR 42912, June 30, 2016) and the 2015 Health Care Antiseptics proposed rule (80 FR 25166, May 1, 2015), as long as they also comply with other applicable requirements.

Accordingly, although the temporary policies are being withdrawn as described above, firms may continue to manufacture alcohol-based hand sanitizer products without an approved application, provided they comply with the applicable TFM and other applicable requirements, including current good manufacturing practice (CGMP) requirements under section 501(a)(2)(B) of the FD&C Act. Under CGMP, among other things, drug product manufacturers are required¹⁴ to test their drug products prior to release to assure that the drug products meet the requirements for safety and have the identity and strength, and meet the quality and purity characteristics, that the drug products purport to possess. We remind distributors, re-packagers, and importers that they are also responsible for the safety and quality of the drugs they introduce into interstate commerce.

Firms preparing alcohol-based hand sanitizer products under FDA's temporary policies (other than compounding pharmacies) had to register their facility and list these products in the FDA Drug Registration and Listing System (DRLS, <https://www.fda.gov/drugs/guidance->

¹³ Under the OTC Drug Review, FDA classified drugs as category III where FDA determined that the available data are insufficient to classify the drug as generally recognized as safe and effective, and further testing is required (see 21 CFR 330.10(a)(5)(iii) and (a)(6)(iii)).

¹⁴ See 21 CFR 211.165 Testing and release for distribution.

compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls).¹⁵ We remind firms that registered and submitted drug product listing(s) for hand sanitizer(s) only but no longer manufacture such product, or plan to cease manufacturing such product, to deregister and delist their hand sanitizer product listing(s) by following the instructions on the Electronic Drug Registration and Listing Instructions page (<https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions>).

To deregister an establishment using CDER Direct:

- Log into your account and open the previously accepted version of the registration submission.
- Click on CREATE NEW VERSION. This will create a copy of the file, keeping the same SetID, but generate a new RootID, Version Number, and Effective Date.
- For Document type, Select ESTABLISHMENT DE-REGISTRATION from the drop-down list.
- Click SUBMIT SPL.

To deregister an establishment from other software applications:

- Create an establishment deregistration SPL document.
- Fill in the SetID with the SetID from your previously accepted version.
- Enter the appropriate effective date and version number (generally, one number higher than the previous submission).
- Submit.

To delist a product using CDER Direct:

- Log into your account and open the previously accepted version of drug listing submission.

¹⁵ Every person required to register with FDA must, at the time of initial registration, list all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution. See section 510(j)(1) of the FD&C Act (21 U.S.C. 360(j)(1)); see also 21 CFR 207.17 and 207.41. Firms that are required to register their foreign establishment with FDA must list all known importers in the United States in their registration in accordance with section 510(i)(1)(A) of the FD&C Act. See also 21 CFR 207.25(h)(2).

- Click on CREATE NEW VERSION. This will create a copy of the file, keeping the same SetID, but generate a new RootID, Version Number, and Effective date.
- Click on the product to edit the Product Data Elements. Change the Marketing Status from “ACTIVE” to “COMPLETED” and enter a Marketing End Date no later than March 31, 2022.
- Save changes and click SUBMIT SPL.

To delist a product from other software applications:

- Open the previously accepted version of drug listing submission.
- Create a new version with the same SetID from your previous submission, but generate a new RootID.
- Enter the appropriate effective date and version number (generally, one number higher than the previous submission).
- Edit the product data elements. Change the Marketing Status from “ACTIVE” to “COMPLETED” and enter a Marketing End Date no later than March 31, 2022.
- Save and Submit.

To request additional assistance with deregistration and delisting, please contact edrls@fda.hhs.gov.

II. Withdrawal Date

The withdrawal date for the three guidance documents discussed in this document is December 31, 2021. Accordingly, firms manufacturing alcohol under the temporary policies for use in alcohol-based hand sanitizers and firms and compounders preparing alcohol-based hand sanitizers under the temporary policies must cease production of these products by December 31, 2021. In addition, firms must by March 31, 2022, cease distribution of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. After March 31, 2022, FDA intends to cease its temporary policy of not taking action with regard to distribution of hand sanitizers or alcohol for use in alcohol-based hand sanitizers

prepared consistent with the circumstances described in the withdrawn guidance documents. The COVID-19 pandemic is a constantly evolving situation. FDA continues to assess these circumstances and should the current data change to indicate that hand sanitizer demand has again outstripped supply prior to December 31, 2021, FDA may alter these dates. However, firms should assume these dates will not change and prepare accordingly for cessation of manufacture and distribution of these products.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. References in the Notice without asterisks are not available electronically at <https://www.regulations.gov> because they have copyright restrictions, but they are on display at the Dockets Management Staff and available for viewing at the location and times noted above. Some may be available at the website address, if any, listed with the reference or such website may provide further information on obtaining copies. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Kang, J., “Retailers Couldn’t Stock Hand Sanitizer Fast Enough. Now They Can’t Give It Away,” *The Wall Street Journal*, May 20, 2021, (available at <https://www.wsj.com/articles/america-is-awash-in-hand-sanitizer-11621522829>), accessed August 30, 2021.

2. Dvorak, P., “Last Year, Hand Sanitizer Was a Precious Commodity. Now They’re Giving It Away,” *The Washington Post*, June 24, 2021 (available at <https://www.washingtonpost.com/local/last-year-hand-sanitizer-was-a-precious-commodity->

now-theyre-giving-it-away/2021/06/24/351f1278-d504-11eb-9f29-e9e6c9e843c6_story.html), accessed August 30, 2021.

3. Bomey, N., “Panic Buying? Not Anymore. Suddenly There’s a Surplus of Hand Sanitizer,” *USA Today*, April 8, 2021 (available at <https://www.usatoday.com/story/money/2021/04/08/hand-sanitizer-deals-donations-surplus-panic-buying-pandemic/7120815002/>), accessed August 30, 2021.

4. * Letter from James Kim and Barbara Kochanowski, ACI/CHPA, to Theresa Michele, FDA, April 28, 2021 (available at <https://www.regulations.gov/comment/FDA-2020-D-1106-0164>), accessed August 30, 2021.

5. Gojo, “PURELL Brand Strongly Positioned to Support Safe Reopening of Schools,” February 22, 2021 (available at <https://www.gojo.com/en/Newsroom/Press-Releases/2021/PURELL-Brand-Strongly-Positioned-to-Support-Safe-Reopening-of-Schools>), accessed August 30, 2021.

6. * Secretary of the Department of Health and Human Services, “Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus,” originally issued January 31, 2020, and subsequently renewed (available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>), accessed August 30, 2021.

Dated: October 5, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.