February 11, 2022

Merck Sharp & Dohme Corp.
Attention: Sushma Kumar, PhD, PMP
Senior Director, Global Regulatory Affairs and Clinical Safety
1 Merck Drive
PO Box 100
Whitehouse Station, NJ 08889-0100

RE: Emergency Use Authorization 108

Dear Dr. Kumar:

This letter is in response to Merck Sharp & Dohme Corp.'s (Merck) request that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of molnupiravir for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 23, the Food and Drug Administration (FDA) issued an EUA for emergency use of molnupiravir as treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

Molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis. Molnupiravir is not FDA-approved for any uses, including use as treatment for COVID-19.

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[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* February 4, 2020.
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

On February 11, 2022, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the December 23, 2021 letter in its entirety, to revise the scope of this authorization to account for the FDA-approval of Veklury (remdesivir) for the treatment of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death.[3] This letter was also revised to include a new condition regarding registration and listing. The authorized Fact Sheets were also revised to reflect the revision to the scope of authorization for molnupiravir as described above and include information on post-authorization reports of hypersensitivity reactions and rashes.

Based on the review of the data from the MOVe-OUT clinical trial (NCT04575597), a Phase III randomized, double-blind, placebo-controlled clinical trial studying molnupiravir for the treatment of non-hospitalized patients with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death, it is reasonable to believe that molnupiravir may be effective for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate, as described in the Scope of Authorization (Section II), and when used under the conditions described in this authorization, the known and potential benefits of molnupiravir outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of molnupiravir for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of molnupiravir for treatment of mild-to-moderate COVID-19, when administered as described in the Scope of Authorization (Section II), meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that molnupiravir may be effective for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (section II), and that, when used under the conditions described in this authorization, the known and

[3] Veklury was not FDA-approved for this use at the time molnupiravir was initially authorized for emergency use. Based on this approval, Veklury is an approved alternative treatment to molnupiravir. See also Note 4.

potential benefits of molnupiravir outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative[4] to the emergency use of molnupiravir for the treatment of mild-to-moderate COVID-19 in adults as further described in the Scope of Authorization (section II).[5]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized molnupiravir will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Merck will supply molnupiravir to authorized distributor(s)[6], who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities as needed;

- Molnupiravir may only be used for the treatment of mild-to-moderate COVID-19 in adults:

    - With positive results of direct SARS-CoV-2 viral testing, and
    - Who are at high-risk[7] for progression to severe COVID, including hospitalization or death, and
    - For whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

    Limitations on Authorized Use

    - Molnupiravir is not authorized for use in patients who are less than 18 years of age.
    - Molnupiravir is not authorized for initiation of treatment in patients requiring hospitalization due to COVID-19.[8] Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19.

[4] Although Veklury (remdesivir) is an approved alternative to treat COVID-19 in adults within the scope of this authorization, FDA does not consider it to be an adequate alternative for certain patients for whom it may not be feasible or practical (e.g., it requires a 3-day treatment duration).
[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[6] "Authorized Distributor(s)" are identified by Merck as an entity or entities allowed to distribute authorized molnupiravir.
[7] For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.
[8] Patients requiring hospitalization after starting treatment with molnupiravir may complete the full 5-day treatment course per the healthcare provider's discretion.

  - Molnupiravir is not authorized for use for longer than 5 consecutive days.
  - Molnupiravir is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.

- Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state[9] law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., anti-infectives).

- The use of molnupiravir covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

The authorized molnupiravir is supplied as a bottle (NDC-0006-5055-06, NDC-0006-5055-07) containing a sufficient quantity of molnupiravir 200 mg capsules to complete a full treatment course (i.e., 40 capsules). Molnupiravir is manufactured as a Swedish Orange, opaque capsule containing the Merck corporate logo and "82" printed in white ink.

The authorized storage and handling information is included in the authorized Fact Sheet for Healthcare Providers.

Molnupiravir is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and to patients and caregivers, respectively, through Merck's website www.molnupiravir.com (referred to as the "authorized labeling"):

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) for molnupiravir
- Fact Sheet for Patients and Caregivers: Emergency Use Authorization (EUA) of molnupiravir for Coronavirus Disease 2019 (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of molnupiravir, when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh the known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that molnupiravir may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that molnupiravir (as

[9] The term "State" includes any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. See section 201(a)(1) of the Act.

described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of molnupiravir product under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), molnupiravir is authorized for the treatment of COVID-19 as described in this Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Merck and Authorized Distributors[10]

A. Merck and authorized distributor(s) will ensure that molnupiravir is distributed and the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers as described in Section II of this Letter of Authorization.

B. Merck and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. Merck and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving molnupiravir. Merck will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. Merck may request changes to this authorization, including to the authorized Fact Sheets for molnupiravir. Any request for changes to this EUA must be submitted to the Office of Infectious Diseases/Office of New Drugs/Center for Drug Evaluation and Research. Such changes require appropriate authorization prior to implementation.[11]

[10] Supra at Note 6.

[11] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study; (8) new strengths of the authorized product, new product sources (e.g., of active pharmaceutical ingredient) or of product components. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), (7), or (8), review and concurrence is required from the Counter-Terrorism and

E. Merck may develop and disseminate instructional and educational materials (e.g., materials providing information on product administration and/or patient monitoring) that are consistent with the authorized emergency use of molnupiravir as described in this Letter of Authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs. Any instructional and educational materials that are inconsistent with the authorized labeling for molnupiravir are prohibited. If the Agency notifies Merck that any instructional and educational materials are inconsistent with the authorized labeling, Merck must cease distribution of such instructional and educational materials. Furthermore, as part of its notification, the Agency may also require Merck to issue corrective communication(s).

F. Merck will report to FDA all serious adverse events and medication errors potentially related to molnupiravir use that are reported to Merck using either of the following options.

   Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

   Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

   Submitted reports under both options must state: "Molnupiravir use for COVID-19 under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

G. All manufacturing, packaging, and testing sites for both drug substance and drug product used for EUA supply will comply with current good manufacturing practice requirements of Section 501(a)(2)(B) of the Act.

H. Merck will submit information to the Agency within three working days of receipt of any information concerning significant quality problems with distributed drug product of molnupiravir that includes the following:

   - Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or
   - Information concerning any microbiological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the product to meet the established specifications.

Emergency Coordination Staff/Office of the Center Director/CDER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

If a significant quality problem affects unreleased product and may also impact product(s) previously released and distributed, then information must be submitted for all potentially impacted lots.

Merck will include in its notification to the Agency whether the batch, or batches, in question will be recalled. If FDA requests that these, or any other batches, at any time, be recalled, Merck must recall them.

If not included in its initial notification, Merck must submit information confirming that Merck has identified the root cause of the significant quality problems, taken corrective action, and provide a justification confirming that the corrective action is appropriate and effective. Merck must submit this information as soon as possible but no later than 45 calendar days from the initial notification.

I. Merck will manufacture molnupiravir to meet all quality standards and per the manufacturing process and control strategy as detailed in Merck's EUA request. Merck will also test the active pharmaceutical ingredient (API) starting material for additional quality attributes agreed upon by Merck and the Agency. Merck will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product, without notification to and concurrence by the Agency as described under condition D.

J. Merck will list molnupiravir with a unique product NDC under the marketing category of Emergency Use Authorization. Further, the listing will include each establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment.

K. Through a process of inventory control, Merck and authorized distributor(s) will maintain records regarding distribution of molnupiravir (i.e., lot numbers, quantity, receiving site, receipt date).

L. Merck will establish a process for monitoring genomic database(s) for the emergence of global viral variants of SARS-CoV-2. A summary of Merck's process should be submitted to the Agency as soon as practicable, but no later than 30 calendar days of the issuance of this letter, and within 30 calendar days of any material changes to such process. Merck will provide reports to the Agency on a monthly basis summarizing any findings as a result of its monitoring activities and, as needed, any follow-up assessments planned or conducted.

M. FDA may require Merck to assess the activity of the authorized molnupiravir against any global SARS-CoV-2 variant(s) of interest (e.g., variants that are prevalent or becoming prevalent that harbor substitutions in the target protein or in protein(s) that interact with the target protein). Merck will perform the required assessment in a manner and timeframe agreed upon by Merck and the Agency. Merck will submit to FDA a preliminary summary report immediately upon completion of its assessment followed by a detailed study report within 30 calendar days of study completion. Merck will submit any relevant proposal(s) to

revise the authorized labeling based on the results of its assessment, as may be necessary or appropriate based on the foregoing assessment.

N. Merck shall provide samples as requested of molnupiravir to the U.S. Department of Health and Human Services (HHS) for evaluation of activity against emerging global viral variants of SARS-CoV-2, including specific amino acid substitution(s) of interest (e.g., variants that are highly prevalent or that harbor substitutions in the target protein) within 5 business days of any request made by HHS. Analyses performed with the supplied quantity of molnupiravir may include, but are not limited to, cell culture potency assays, biochemical assays, and in vivo efficacy assays.

O. Merck must provide the following information to the Agency:

1. Merck will conduct a thorough investigation into the differences in efficacy observed in the first and second half of Part 2 of trial MK-4482-002. This assessment should involve the synthesis of data, including, but not limited to, additional baseline serology testing, a detailed comparison of baseline characteristics (including demographic, clinical disease, and virologic characteristics), and an exploration of potential differences in standard of care by region and over time. Merck will submit a report of its findings to the Agency. Merck will submit a preliminary report no later than March 31, 2022 and a final report incorporating available serology results no later than September 30, 2022.
2. Merck will submit the complete viral shedding results and full genome SARS-CoV-2 nucleotide sequencing results from the full randomized population in study MK-4482-002 Part 2. Viral sequencing analyses should include all Baseline and End-of-Treatment (Day 5) samples with sufficient RNA levels for analysis, as well as all Post-Treatment samples with viral RNA levels ≥100,000 copies/mL. Cell culture infectivity assessments should be conducted for any clinical specimens in which amino acid changes were detected in the SARS-CoV-2 spike protein. Submissions should include summary report(s) and associated datasets (including analysis-ready datasets and raw fastq NGS data). A separate summary should be provided describing the results of the viral shedding and sequencing analyses specifically from immunocompromised patients. Merck will submit a preliminary report and associated datasets for the viral shedding and Baseline/Day 5 sequencing analyses no later than March 31, 2022, and a final report and datasets including the remaining analyses no later than June 30, 2022.
3. Merck will evaluate the cell culture antiviral activity of molnupiravir against an authentic SARS-CoV-2 isolate representative of the Omicron variant. Merck must submit a study report no later than February 28, 2022.
4. Merck will conduct a pharmacokinetic (PK) study in wild type Fisher 344 rats to establish if NHC or NHC-TP is detected in testes. The study should include plasma exposure levels that meet/exceed the human exposure for NHC. Merck will submit the results of the PK study no later than March 31, 2022.

- If the results of the PK study demonstrate NHC or NHC-TP distribution to testes, Merck will also conduct a male germ cell mutation assay in the Big Blue rat model. Merck must submit a protocol for the Big Blue rat assay no later than 30 days after the PK results are submitted to FDA, or by April 30, 2022. Results from the Big Blue rat assay will be submitted no later than July 31, 2023.

P. Merck must maintain a pregnancy surveillance program to collect information through telephone and online reporting of pregnancies and collect outcomes for individuals who are exposed to molnupiravir during pregnancy. Merck must submit to the Agency reports detailing any available exposure information and outcome(s) data on a monthly basis unless otherwise notified by FDA.

Q. Merck and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom Molnupiravir Is Distributed and Healthcare Providers Administering Molnupiravir

R. Healthcare facilities and healthcare providers will ensure that they are aware of the Letter of Authorization, and the terms herein. Healthcare providers must provide and document that a copy of the authorized Fact Sheet for Patients and Caregivers has been provided, either through electronic means or hardcopy, to the patient or caregiver prior to prescribing molnupiravir.

S. Healthcare providers must inform patients or caregivers of the information detailed in the section *Mandatory Requirements for Administration of Molnupiravir Under Emergency Use Authorization* in the Fact Sheet for Healthcare Providers.

T. Molnupiravir may only be prescribed to a pregnant individual after the prescribing healthcare provider has completed the mandatory requirements on patient assessment, patient counseling, and documentation as described in the Fact Sheet for Healthcare Providers. See *Mandatory Requirements for Administration of Molnupiravir Under Emergency Use Authorization* in the Fact Sheet for Healthcare Providers.

U. Healthcare providers must inform and document that pregnant individuals who are prescribed molnupiravir have been made aware of Merck's pregnancy surveillance program as detailed in the authorized Fact Sheets. If the pregnant individual agrees to participate in the pregnancy surveillance program and allows the prescribing healthcare provider to disclose patient specific information to Merck, the prescribing healthcare provider must provide the patient's name and contact information to Merck at 1-877-888-4231 or pregnancyreporting.msd.com.

V. Healthcare facilities and healthcare providers receiving molnupiravir will track all serious adverse events and medication errors that are considered to be potentially related to molnupiravir use and must report these to FDA in accordance with the Fact Sheet for

Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports must state, "Molnupiravir use for COVID-19 under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis.

W. Healthcare facilities and healthcare providers will ensure that appropriate storage is maintained until the product is administered consistent with the terms of this letter and the authorized labeling.

X. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensing and administration of molnupiravir for the use authorized in this letter (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

Y. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Merck and/or FDA. Such records will be made available to Merck, HHS, and FDA for inspection upon request.

Z. Healthcare facilities and providers will report therapeutics information and utilization data as directed by HHS.

Conditions Related to Printed Matter, Advertising, and Promotion

AA. All descriptive printed matter, advertising, and promotional materials relating to the use of molnupiravir under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the Act, as applicable, and FDA implementing regulations. References to "approved labeling", "permitted labeling" or similar terms in these requirements shall be understood to refer to the authorized labeling for the use of molnupiravir under this authorization. In addition, such materials shall:

- Be tailored to the intended audience.
- Not take the form of reminder advertisements, as that term is described in 21 CFR 202.1(e)(2)(i), 21 CFR 200.200 and 21 CFR 201.100(f).
- Present the same risk information relating to the major side effects and contraindications concurrently in the audio and visual parts of the presentation for advertising and promotional materials in audio-visual format.
- Be accompanied by the authorized labeling, if the promotional materials are not subject to Section 502(n) of the Act.
- Be submitted to FDA accompanied by Form FDA-2253 at the time of initial dissemination or first use.

If the Agency notifies Merck that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions AA through CC of this EUA, Merck must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require Merck to issue corrective communication(s).

BB. No descriptive printed matter, advertising, or promotional materials relating to the use of molnupiravir under this authorization may represent or suggest that molnupiravir is safe or effective when used for the treatment of COVID-19.

CC. All descriptive printed matter, advertising, and promotional material, relating to the use of molnupiravir under this authorization clearly and conspicuously shall state that:

- Molnupiravir has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate; and

- The emergency use of molnupiravir is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration