defects. Because we expect that most such gloves are imported, FDA's focus will be on products at the time of importation. We also draw your attention to the guidance from 2008 entitled ''Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves'', which also discusses the acceptable quality criteria defined in 21 CFR 800.20 for the importation of gloves (Ref. 9). Nothing in this Notice alters the legal obligation to comply with the relevant statutory requirements and does not preclude the Agency from taking action to enforce those requirements where appropriate.

If the gloves discussed in this notice meet the reserved criteria, such gloves require a 510(k). Following consideration of the comments, FDA intends to issue a future notice in the **Federal Register** containing its final determination concerning whether these seven types of gloves are reserved. Previously, during 510(k) review for these types of gloves, FDA has evaluated the dimensional and physical properties of the gloves, and nonclinical data regarding barrier performance, biocompatibility, and residual powders, among other information, to support the safety and effectiveness of the gloves for their intended use. FDA also evaluates the indications for use and labeling to ensure the devices are appropriately labeled, consistent with their intended use. For any gloves that are distributed after FDA issues its final determination, the Agency would consider and take appropriate enforcement action, taking into account the enforcement policy in the Gloves PHE Guidance.

VI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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. Centers for Disease Control, ''Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings.'' *Morbidity and Mortality Weekly Report,* 1988; 37(25):377–388.
2. World Health Organization, ''Glove Use Information Leaflet.'' 2009. *https://www.who.int/gpsc/5may/Glove_Use_Information_Leaflet.pdf.*
3. Collins, A.S., ''Preventing Health Care-Associated Infections.'' In: Hughes, R.G., Ed. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses.* Rockville (MD): Agency for Healthcare Research and Quality (U.S.); April 2008, chapter 41.
4. Alexander, J.W., J.S. Solanki, and M.J. Edwards, ''Updated Recommendations for Control of Surgical Site Infections,'' *Annals of Surgery,* 253(6):1082–1093, 2011.
5. Sugarbaker, P.H., ''Increased Safety of Surgical Glove Application: The Under/Over Method,'' *Annals of the Royal College of Surgeons of England,* 100(4):339–340, 2018.
6. Landeck, L., E. Gonzalez, and O.M. Koch, ''Handling Chemotherapy Drugs—Do Medical Gloves Really Protect?'' *International Journal of Cancer,* 137(8):1800–1805, 2015. doi: 10.1002/ijc.29058. Epub 2014 July 22. PMID: 24978061.
7. Nalin, M., G. Hug, E. Boeckmans, et al., ''Permeation Measurement of 27 Chemotherapy Drugs After Simulated Dynamic Testing on 15 Surgical and Examination Gloves: A Knowledge Update,'' *Journal of Oncology Pharmacy Practice,* 2020 August 26:1078155220950423. doi: 10.1177/1078155220950423. Epub ahead of print. PMID: 32847481.
8. *FDA Guidance for Industry and FDA Staff, ''Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency,'' March 2020; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.*
9. *FDA Guidance for Industry and FDA Staff, ''Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves,'' July 2008; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surveillance-and-detention-without-physical-examination-surgeons-and-or-patient-examination-gloves.*

Dated: April 12, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: April 12, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–07759 Filed 4–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0275]

Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the following public workshop entitled ''Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions.'' The purpose of the workshop is to bring stakeholders together to discuss the scientific basis of morphine milligram equivalents (MMEs) with the goals of providing an understanding of the science and data underlying existing MME calculations for opioid analgesics, discussing the gaps in these data, and discussing future directions to refine and improve the scientific basis of MME applications.

DATES: The public workshop will be held virtually and via webcast on June 7 and 8, 2021, from 9 a.m. to 5 p.m. Eastern Time each day. Submit either electronic or written comments on this public workshop by August 9, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public workshop via an online teleconferencing platform.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 9, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 9, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0275 for ''Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure laws. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kimberly Compton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3168, Silver Spring, MD 20993–0002, 301–796–1191, *kimberly.compton@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Opioid analgesics vary in analgesic efficacy and potential for harm. MMEs or other similar conversion factors are used often to quantify potency across opioids, usually compared to oral morphine. MME tables were originally developed as an adjunct to clinical judgment to inform starting doses when switching patients between different opioid analgesics. However, MMEs are increasingly being used to indicate abuse and overdose potential and to set thresholds for prescribing and dispensing of opioid analgesics. FDA is convening this public workshop to discuss the current landscape and science underlying MMEs and their uses.

II. Topics for Discussion at the Public Workshop

This public workshop will provide: (1) An overview of the landscape of MMEs, starting with a historical perspective of how MMEs were originally developed and intended to be used; (2) the data informing published resources on MMEs; (3) the development and intended use of commonly-referenced sources, such as the Centers for Disease Control and Prevention's resources; (4) the current uses of MMEs and gaps in knowledge; and (5) future directions to refine and improve the scientific basis of MME applications.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website to register: *https://morphinemilligram equivalent.eventbrite.com*. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free.

If you need special accommodations due to a disability, please contact Kimberly Compton (see **FOR FURTHER INFORMATION CONTACT**) no later than May 17, 2021.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. Submit a brief statement of the topic you wish to address and the names and addresses of proposed participants. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make oral presentations must be received by May 24, 2021. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by May 31, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled public comment session, FDA may conduct a lottery to determine the speakers for the scheduled public comment session. If selected for presentation, any presentation materials must be emailed to Kimberly Compton (see **FOR FURTHER INFORMATION CONTACT**) no later than June 3, 2021. No commercial or promotional material

will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. Additional information will be made available regarding accessing the webcast before the public workshop at *https://morphinemilligram equivalent.eventbrite.com* and at *https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and*. All other meeting materials, including agenda, will be available before the workshop at *https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and*.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview*. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/morphine-milligram-equivalents-current-applications-and-knowledge-gaps-research-opportunities-and*.

Dated: April 12, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07837 Filed 4–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–Z–0025]

Making Permanent Regulatory Flexibilities Provided During the COVID–19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Withdrawal of Proposed Exemptions

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Notice of withdrawal.

SUMMARY: The Department of Health and Human Services (HHS or ''The Department'') issued a Notice in the **Federal Register** of January 15, 2021, that, among other things, proposed to exempt 83 class II devices and 1 unclassified device from premarket notification. This Notice announces HHS's and the Food and Drug Administration's (FDA or ''the Agency'') withdrawal of the proposed exemptions for the 83 class II devices and 1 unclassified device. The comment period for the proposed class II and unclassified device exemptions closed on March 15, 2021. HHS and FDA are withdrawing the proposed exemptions after reviewing the Notice, its comments, inquiries to FDA, and other relevant information, and determining that the proposed exemptions and bases for them are flawed.

DATES: The proposed exemptions of 83 class II devices and 1 unclassified device, published on January 15, 2021 (86 FR 4088), are withdrawn as of April 16, 2021.

FOR FURTHER INFORMATION CONTACT: Angela Krueger, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1660, Silver Spring, MD 20993, 301–796–6380, or by email at *RPG@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (''1976 amendments'') (Pub. L. 94–295), and the Safe Medical Devices Act of 1990 (Pub. L. 101–629), devices are classified into class I (''general controls'') if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (''special controls''), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic device types that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as ''preamendments devices'') have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as ''postamendments devices''), are generally classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations in 21 CFR part 807 require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

Section 510(m)(2) of the FD&C Act allows FDA, on its own initiative or in response to an exemption petition, to issue in the **Federal Register** a notice of intent to exempt any type of class II device from the requirement to submit a report under section 510(k) of the FD&C Act, if the Agency determines that such a report is not necessary to assure the safety and effectiveness of the device. Section 510(m)(2) further provides that the public may comment on FDA's proposed exemptions for 60 days after publication in the **Federal Register** and that FDA shall issue an order setting forth the final determination within 120 days.

In addition, section 510(m)(1)(A) of the FD&C Act requires FDA to, within