Respondents: The baseline and follow-up surveys will be administered to youth in the treatment group (youth receiving the Pathways program) and youth in the control group who consent to participate in the study. Interviews will be conducted with program leadership and staff. Focus groups will be conducted with a subset of youth who are participating in the study. Check-ins will be conducted with program directors.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
SYSIL Youth Survey—Baseline survey	700	1	.5	350	117
SYSIL Youth Survey—Follow-up survey 1 (6 months)	630	1	.5	315	105
SYSIL Youth Survey—Follow-up survey 2 (12 months)	595	1	.5	298	99
SYSIL Youth Survey—Follow-up survey 3 (24 months)	490	1	.5	245	82
Interview guide for Pathways sites (treatment sites)	30	1	1.5	45	15
Program Director Check-ins for Pathways sites (treatment sites)	6	2	.5	6	2
Interview guide for comparison sites	30	1	1.5	45	15
Program Director Check-ins for comparison sites	6	2	.5	6	2
Focus group discussion guide for Pathways youth (treatment youth)	50	1	1.5	75	25
Focus group discussion guide for comparison youth	50	1	1.5	75	25

Estimated Total Annual Burden Hours: 487.

Authority: Section 105(b)(5) of the Child Abuse Prevention and Treatment Act (CAPTA) of 1978 (42 U.S.C. 5106(b)(5)), as amended by the CAPTA Reauthorization Act of 2010 (Pub. L. 111–320).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–07752 Filed 4–15–21; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–Z–0025]

Medical Devices; Class I Surgeon's and Patient Examination Gloves

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

ACTION: Notice; request for comments.

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, identified seven types of reserved class I devices that the Department had determined no longer require premarket notification. The Department and the Food and Drug Administration (FDA or ''the Agency'') have reviewed the prior determination, including the record supporting it, and believe that the determination is flawed. This notice explains the basis for HHS and FDA's current view that the seven types of reserved class I devices identified in the January 15, 2021, Notice require a premarket notification, and explains why the reasoning supporting the prior determination was unsound. HHS and FDA are seeking comment on the matters discussed in this notice and will issue a future notice in the **Federal Register** containing a final determination regarding the class I medical gloves listed in the January 15, 2021, Notice.

DATES: Submit either electronic or written comments on this Notice by May 17, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Comments must be submitted by May 17, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 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–Z–0025 for ''Medical Devices; Class I Reserved Surgeon's and Patient Examination Gloves.'' 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 law. 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: Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1660, Silver Spring, MD 20993, 301–796–6380, *RPG@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Regarding Section 510(l) of the FD&C Act

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 (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.

Unless a device is exempt from premarket notification, section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, part 807 (21 CFR part 807), require persons who intend to market a new device to submit a premarket notification (510(k)) demonstrating that 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(*l*) of the FD&C Act, added to the statute by the Food and Drug Administration Modernization Act of 1997 (FDAMA and now codified as section 510(*l*)(1), provides that a 510(k) is not required for a class I device, except for a class I device intended for a use that is of substantial importance in preventing impairment of human health, or any class I device that presents a potential unreasonable risk of illness or injury. FDA refers to these as the ''reserved criteria'' and to class I devices subject to 510(k) as ''class I reserved devices.'' Thus, class I devices are exempt from the 510(k) requirements unless a class I device type meets the reserved criteria under section 510(*l*)(1) of the FD&C Act.

After the enactment of FDAMA, FDA evaluated all class I devices in interstate commerce at that time to determine which device types met the reserved criteria. On February 2, 1998, FDA published in a notice in the **Federal Register**: (1) A list of device types that FDA believed met the reserved criteria and thus would remain subject to premarket notification and (2) a list of device types that FDA believed did not meet these criteria and thus would be exempt from such requirement as of February 19, 1998 (the statutory effective date for what is now section 510(*l*)(1)) (63 FR 5387). As part of the evaluation, where FDA determined a device type did not meet the reserved criteria, FDA also considered limitations on that exemption—that is, the circumstances under which an exempt device could, depending on the device's intended use or potential unreasonable risk, meet the reserved criteria and thus remain subject to the premarket notification requirement (63 FR 5387 at 5388 to 5389). Although devices that did not meet the reserved criteria became exempt on February 19, 1998, the February 2, 1998, notice invited public comment on FDA's determinations concerning the status of various class I devices. On November 12, 1998, FDA published a proposed rule to amend the applicable classification regulations in the Code of Federal Regulations to designate which class I devices require premarket notification and which devices are exempt from premarket notification under section 510(*l*) of the FD&C Act (63 FR 63222). This took into account FDA's determinations in the February 1998 notice, comments received in response to that notice, and other information available to the Agency. At the same time, FDA evaluated devices the Agency had, prior to FDAMA, exempted from the premarket notification requirement by rulemaking. FDA determined that five such device types met the reserved criteria and thus proposed to amend the applicable classification regulations accordingly (63 FR 63222). FDA issued a final rule amending those classification regulations on January 14, 2000 (65 FR 2296).

On December 13, 2016, the 21st Century Cures Act (Cures Act) amended section 510(*l*) of the FD&C Act, reorganizing section 510(*l*) into subsections 510(*l*)(1) and (2). Section 510(*l*)(2) of the FD&C Act requires FDA to identify at least once every 5 years, through publication in the **Federal Register**, any type of class I device that the Agency determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(*l*)(2) of the FD&C Act further provides that upon publication of the Agency's determination in the **Federal Register**, these devices shall be exempt from 510(k) and the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption. Following the enactment of the Cures Act, FDA published in a notice in the **Federal Register** a list of

class I device types that it had determined no longer meet the reserved criteria and are thus exempt from 510(k) (82 FR 17841, April 13, 2017). In 2019, FDA amended the classification regulations to reflect the exemption determinations (84 FR 71794, December 30, 2019). That final order and amendment also addressed exemption determinations for class II devices, which are subject to a different process.

II. Criteria for Exemption From Section 510(k) of the FD&C Act

FDA has explained, following the enactment of both FDAMA and the Cures Act, that it determines whether class I devices are subject to, or exempt from, 510(k) based on the reserved criteria. The Department concurs. As previously noted, the statute sets forth the relevant criteria for when a class I device is subject to section 510(k) of the FD&C Act. Specifically, section 510(*l*)(1) of the FD&C Act provides that a class I device is not exempt from the premarket notification requirements of section 510(k) if the device is intended for a use that is of substantial importance in preventing impairment of human health, or it presents a potential unreasonable risk of illness or injury (63 FR 5387, 82 FR 17841).

Because all devices must have a reasonable assurance of safety and effectiveness (see discussion regarding classification and the level of regulation necessary to provide such assurance in section I of this document), the reserved criteria delineate which class I devices require a 510(k) to provide a reasonable assurance of safety and effectiveness and which do not. Thus, the directive in section 510(*l*)(2) of the FD&C Act that FDA must identify class I devices it determines no longer require a report under section 510(k) to provide reasonable assurance of safety and effectiveness means that FDA must identify which class I devices that FDA previously determined meet the reserved criteria no longer meet these criteria, in which case a 510(k) is no longer required to provide reasonable assurance of safety and effectiveness. FDA has explained that in determining whether either of these criteria are met, the Agency considers for example, its experience in reviewing premarket notifications for each device, focusing on the risk inherent with the device and the disease being treated or diagnosed (*e.g.,* devices with rapidly evolving technology or expansions of intended uses) (63 FR 5387, 82 FR 17841). The Agency also considers the history of adverse event reports under the medical device reporting program for these devices, as well as their history of product recalls.

III. Determination Regarding Surgeon's Gloves and Patient Examination Gloves and Premarket Notification

Based on the risks inherent with surgeon's gloves and patient examination gloves and the diseases being prevented, FDA's experience with these devices, and other relevant considerations, HHS and FDA believe that gloves with the product codes LYY, LYZ, OIG, OPC, OPH, LZC, and OPA are intended for uses which are of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury and thus require a report under section 510(k) of the FD&C Act. Surgeon's gloves and patient examination gloves are generally intended to prevent contamination and the spread of pathogens (see 21 CFR 878.4460 and 880.6250). They can be the key barrier that protects against the spread of infection between individuals, including infections transmitted through bodily fluids, such as hepatitis or human immunodeficiency virus (HIV) (Refs. 1–3). Surgeon's gloves, in particular, prevent against contamination in the operating room, where patients are highly vulnerable to infection (Refs. 4 and 5). Medical gloves also serve other key purposes, such as protecting against occupational exposure to chemotherapy drugs, which have potential mutagenic, carcinogenic, and teratogenic effects (Refs. 6 and 7). Thus, these gloves play an important role in preventing risks to the public, and 510(k) review is necessary to provide reasonable assurance of their safety and effectiveness, including by helping to assure that the gloves are durable and impermeable, among other things.

Because of their importance in preventing impairment of human health, FDA has long considered these seven types of gloves to meet the reserved criteria under section 510(*l*) of the FD&C Act and to be subject to the 510(k) requirement. In 1998, after considering its experience in reviewing premarket notifications for those devices, as well as the history of adverse event reports and recalls, FDA determined that surgeon's gloves and patient examination gloves meet the reserved criteria (63 FR 5387). FDA invited comments on the February 2, 1998, Notice, and received no comments regarding gloves. When FDA proposed to amend the classification regulations in November 1998 to reflect its determinations as to which class I devices were exempt and which were not (63 FR 63222), FDA again received no comments regarding these surgeon's gloves and patient examination gloves. FDA's January 2000 final rule to amend the classification regulations reflected this determination (65 FR 2296).

Following the enactment of the Cures Act, in 2017, FDA again evaluated all class I reserved devices to determine whether they continued to meet the reserved criteria. In doing so, FDA identified a number of class I devices that, based on the considerations discussed above, do not meet those criteria and thus no longer require premarket notification (82 FR 17841). FDA also considered applicable limitations for the device types that it determined were exempt. During this evaluation, FDA specifically considered the seven types of gloves discussed above. FDA took into account its experiences with 510(k) submissions for the gloves, the risk inherent with the devices and the diseases they prevent, and other relevant considerations. After conducting this evaluation, FDA determined that surgeon's gloves and patient examination gloves met the reserved criteria and therefore remained subject to premarket notification.

FDA has issued an enforcement policy concerning these gloves in response to the COVID–19 public health emergency (PHE). However, this policy, which is limited in duration and scope, is fundamentally different from a determination that the gloves no longer meet the reserved criteria or otherwise no longer require a 510(k). Enforcement policies communicate an Agency's nonbinding views about how it should allocate its enforcement resources based on current facts and circumstances. Such policies do not alter the legal obligation to comply with the relevant requirements and do not preclude the Agency from taking action to enforce those requirements where appropriate. This particular enforcement policy was issued in response to a highly unusual set of facts and circumstances: The most sweeping PHE to occur in over a century. The public health threat posed by COVID–19, the disease caused by the SARS-CoV–2 virus, is substantial. Global demand for infection control measures has increased significantly and is a critical part of the response to the COVID–19 outbreak. FDA's March 2020 guidance entitled ''Enforcement Policy for Gown, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency'' (''Gloves PHE Guidance'') provides information, recommendations, and policies to help address the urgent need for appropriate clinical management and infection control and to help

expand the availability of surgical apparel for healthcare professionals during the COVID PHE (Ref. 8).

Specifically for gloves, the guidance explains that it should help expand the availability of certain gloves to help address the urgent public health concerns caused by shortages of such products by taking a risk-based approach to them. In issuing this policy, FDA sought to balance the various public health considerations related to the PHE and specifically limited the policy to the duration of the PHE. As part of this balancing, the Agency also limited the enforcement policy in scope. In the guidance, FDA stated its intention not to object to the distribution and use of certain patient examination gloves [1] and surgeon's gloves [2] that do not comply with the premarket notification requirements of section 510(k) where the products ''do not create an undue risk in light of the public health emergency.'' FDA then identified factors in determining whether such gloves could create undue risk, such as whether the gloves are labeled for use with chemotherapy drugs, fentanyl, and other opioids, use for allergy or dermatitis prevention, use for antimicrobial or antiviral protection, or use for infection prevention or reduction.

As with all FDA guidance, the Agency invited public comment at any time. FDA has not received any comments on the guidance that such gloves, rather than being subject to an enforcement policy, should be exempt from the premarket notification requirement because they do not meet the reserved criteria. More broadly, given the context in which the guidance was issued and the limitations in its scope and duration, this policy does not diminish the important legal and policy reasons for determining that surgeon's gloves and patient examination gloves are required to have a 510(k). If in March 2020 FDA had believed that the gloves no longer met the reserved criteria and thus were exempt under the statute, the Agency could have undertaken the process specified in 510(*l*)(2) of the FD&C Act; instead it chose an enforcement policy, which reflected FDA's careful balancing of the public-health considerations in response to the PHE.

[1] The policies in the Gloves PHE Guidance apply to those patient examination gloves with product codes FMC, LYY, LZA, LZB, LYZ, OIG, OPC, OPH, and LZC.

[2] The policies in the Gloves PHE Guidance apply to those surgeon's gloves with product codes KGO and OPA.

IV. Issues Raised by HHS's January 15, 2021, Notice

On January 15, 2021, HHS published a notice (''the January 15, 2021, Notice'' or ''Notice'') (86 FR 4088) determining that six types of reserved class I patient examination gloves with the product codes LYY, LYZ, OIG, OPC, OPH, and LZC, and one type of reserved class I surgeon's glove device with the product code OPA, no longer require a report under section 510(k) of the FD&C Act. We did not find any evidence that HHS consulted with, otherwise involved, or even notified FDA before issuing the Notice. The Notice explained that HHS based these exemption determinations on its conclusion that premarket notification is no longer required to provide reasonable assurance of the safety and effectiveness of these devices, which it in turn based solely on its evaluation of adverse events in FDA's Manufacturer and User Facility Device Experience database (MAUDE). HHS concluded that the fact that there were few if any (depending on the glove type) adverse events reported in MAUDE following FDA's issuance of its Gloves PHE Guidance meant that premarket notification is no longer required to provide a reasonable assurance of the safety and effectiveness of these devices. The January 15, 2021, Notice did not discuss any applicable limitations on the exemption for gloves, or even discuss whether it considered that issue.

HHS and FDA have now reexamined the January 15, 2021, Notice, including its class I exemption determinations, and believes it is appropriate to reverse these determinations. This reexamination was prompted primarily by two things. One is that certain staff and leadership in FDA's Center for Devices and Radiological Health that conduct regulatory oversight of personal protective equipment, including the types of gloves covered in the Notice, identified the flaws below and brought them to the Department's attention. The other is that HHS has received dozens of inquiries about the January 15, 2021, Notice, both formally through *https://www.regulations.gov* as well as directly to the contact listed in that Notice and to various FDA staff and FDA program email addresses.

Comments received regarding the seven types of gloves support HHS and FDA's position that these gloves remain subject to 510(k). Generally, comments received to date note the risk of leaching chemotherapy drugs, the risk of radiation exposure, and the importance of barrier protection from infection. One comment remarked on the unreliability of adverse event data alone. Further, the direct inquiries indicate a pattern of uncertainty about whether the class I devices described in the Notice are exempt. In addition, some commenters expressed confusion about the Notice, such as why the Notice discussed some, but not all, of the product codes for surgeon's gloves and patient examination gloves covered by the Gloves PHE Guidance. For example, some commenters asked whether this was intentional or inadvertent, finding no explanation in the Notice. Other inquiries asked whether, regardless of the Notice, FDA would review new 510(k) premarket notifications voluntarily submitted for such devices and/or whether FDA would continue its review of already-submitted premarket notifications. HHS and FDA believe that the determinations in the January 15, 2021, Notice lack adequate legal and scientific support, and that the Notice is otherwise flawed, for the reasons explained below.

First, the January 15, 2021, Notice neither discusses the reserved criteria nor explains how HHS came to determine the gloves no longer meet the reserved criteria; *i.e.,* that the gloves are not intended for a use that is of substantial importance in preventing impairment of human health, or do not present a potential unreasonable risk of illness or injury. The January 15, 2021, Notice contains no mention of or cite to this statutory standard, nor an explanation as to why it was left out. Moreover, even under the standard applied—''reasonable assurance of safety and effectiveness''—the Notice did not consider the gloves' effectiveness.

Second, as mentioned above, in evaluating a device to determine whether it is exempt, FDA has considered its experience in reviewing premarket notifications, focusing on the risk inherent with the device and the disease being treated or diagnosed, as well as other relevant considerations, including the history of adverse event reports for these products and their history of product recalls. The January 15, 2021, Notice, however, HHS relied solely upon adverse event reports in MAUDE as its basis for determining the products to be exempt from 510(k). Although adverse event reports are a valuable source of information, the reports have limitations, as noted in the January 15, 2021, Notice, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. The incidence or prevalence of an event cannot be determined from adverse event reports alone, due to underreporting of events, inaccuracies in reports, lack of

verification that the device caused the reported event, and lack of information about frequency of device use. Adverse event data is not adequate on its own for assessing safety, let alone whether to determine a device to be exempt from 510(k). The Notice does not, for example, take into account FDA's experience in reviewing 510(k)s for these devices, which FDA typically does with a focus on the risk inherent with the device and the relevant disease(s) being treated or diagnosed, or the products' recall history. FDA recognized, in a previous regulatory action, that certain gloves may pose an unreasonable risk of illness or injury when it banned powdered surgeon's gloves and powdered patient examination gloves (see 81 FR 91722, December 19, 2016).

Further, even on its own terms, the adverse event information proffered to support the January 15, 2021, Notice has key limitations. For example, some subset of the gloves on the market following issuance of the Gloves PHE Guidance would have entered the market prior to issuance of the guidance and thus gone through 510(k) review. For that subset, there is no reason to anticipate any change in adverse event reports based on the guidance because they were cleared by FDA. The January 15, 2021, Notice assumes that new or modified gloves, which had never undergone 510(k) review, entered the market following the Gloves PHE Guidance in significant enough proportions that they would skew the adverse-event trends had 510(k) been necessary to assure safety and effectiveness. But the Notice does not explain the basis for this assumption. There is no indication the adverse event evaluation considered whether or how many new or changed gloves entered the market during this time that would justify the Notice's overall conclusions. In addition, the Notice did not explain why it was reasonable to draw conclusions based on adverse events for these products in such a narrow time period, which was from whenever any new or modified gloves started to be used after the March 30, 2020, guidance until November 30, 2020, which was the end of the adverse event review period. Likewise, the Notice did not address other potential data limitations, such as the likelihood that adverse event reporting has been more difficult during a public health emergency and thus may have been more limited than usual. FDA discussed the challenges of adverse event reporting during a pandemic in its guidance, issued in May 2020, entitled, ''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic.'' [3]

Finally, we did not find any evidence that HHS consulted with or otherwise involved FDA in its exemption determination or issuance of the Notice. Section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) provides that the Secretary ''shall be responsible for executing'' the FD&C Act ''through the [FDA] Commissioner.'' Here, the Notice is clearly an action ''executing'' the FD&C Act. Moreover, it is particularly important that FDA have at least some level of involvement in this type of an action given the expertise needed to evaluate whether particular device types meet the reserved criteria.

In evaluating whether the gloves discussed in the January 15, 2021, Notice require a report under section 510(k) of the FD&C Act, the Department and FDA have considered regulated entities' reliance on the Notice. As an initial matter, HHS and FDA observe that, as described above, the Notice contained a number of flaws that have led to significant questions about the status of these devices. HHS and FDA have not only received over 60 inquiries about the Notice, reflecting a pattern of uncertainty, but have also received requests for review of 510(k) premarket notifications that have been voluntarily submitted for such devices. Based on these facts, HHS and FDA believe that only a limited subset of regulated entities may have placed legitimate reliance on the January 15, 2021, Notice. For any such entities, given the short time period between now and when the Notice was issued, HHS and FDA also believe that few (if any) long-term investments, contracts, or other significant business decisions relying on the Notice are likely to have been made. Furthermore, to the extent that any such decisions have been made, HHS and FDA strongly believe that those interests cannot outweigh the directive of the statute for FDA to review class I devices that meet the reserved criteria, and also cannot outweigh the public-health importance of conducting 510(k) review for these devices, for the reasons discussed in section III above. Elsewhere in this issue of the **Federal Register**, HHS and FDA are announcing the withdrawal of the proposed exemptions for the 83 class II devices and 1 unclassified device included in the January 15, 2021, Notice.

[3] Although January 15, 2021, Notice concluded that 510(k)s are no longer necessary for these devices ''[i]n view of the complete lack of or de minimis number of adverse events in MAUDE following [the March 2020 Gloves PHE Guidance],'' the adverse event tables in the Notice included adverse events going back to 2010. To the extent that the quantity of adverse events between 2010 and 2020 informed the conclusion in the Notice regarding the need for 510(k) for the class I gloves, the discussion in this paragraph would not apply. However, this would not impact our analysis of the other flaws in the Notice or our view that these gloves meet the reserved criteria.

V. Further Information for Regulated Entities

HHS and FDA are concerned about the public health risks posed by the January 15, 2021, Notice, particularly as the Notice applies to medical gloves that could pose undue risk as described in the Gloves PHE Guidance. HHS and FDA remind regulated entities that various requirements under the FD&C Act and FDA regulations apply to the class I medical gloves described in this notice, regardless of their status under section 510(k) and (*l*). For example, section 502(a) and (f)(1) of the FD&C Act prohibits device labeling that is false or misleading in any particular or that lacks adequate directions for use (21 U.S.C. 352(a) and (f)(1)). Section 201(n) of the FD&C Act provides that, in determining whether labeling is misleading, ''there shall be taken into account (among other things) not only representations made or suggested. . .but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article. . . .'' (21 U.S.C. 321(n)). FDA regulations further provide that ''[a]mong representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic'' (21 CFR 801.6). Regulated entities should bear in mind that device labeling that makes certain representations or fails to disclose certain information could misbrand the product in violation of the FD&C Act and FDA regulations. FDA emphasizes the importance of compliance with these requirements with respect to the gloves that are the subject of this notice. For more information concerning the labeling of class I medical gloves during the COVID–19 PHE, please see the Gloves PHE Guidance.

Furthermore, because of the potential risks posed by gloves that have not undergone FDA's premarket review, FDA intends to increase its surveillance of the seven types of gloves subject to the January 15, 2021, Notice, taking into account its enforcement policy in the Gloves PHE Guidance. This increased surveillance could, for example, include a labeling review and a physical examination to assess for physical

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.

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2. World Health Organization, ''Glove Use Information Leaflet.'' 2009. *https://www.who.int/gpsc/5may/Glove_Use_Information_Leaflet.pdf.*
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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.

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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: