



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 878, 880, and 895

[Docket No. FDA-2015-N-5017]

RIN 0910-AH02

Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling.

Consequently, FDA is banning these devices.

DATES: This rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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I. Executive Summary

A. Purpose and Coverage of the Final Rule

Medical gloves play a significant role in the protection of both patients and health care personnel in the United States. Health care personnel rely on medical gloves as barriers against transmission of infectious diseases and contaminants when conducting surgery, as well as when conducting more limited interactions with patients. Various types of powder have been used to lubricate gloves so that wearers could don the gloves more easily. However, the use of powder on medical gloves presents numerous risks to patients and health care workers, including inflammation, granulomas, and respiratory allergic reactions.

A thorough review of all currently available information supports FDA's conclusion that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove should be banned. FDA has concluded that the risks posed by powdered gloves, including health care worker and patient sensitization to natural rubber latex (NRL) allergens, surgical complications related to peritoneal adhesions, and other adverse health events not necessarily related to surgery, such as inflammatory responses to glove powder, are important, material, and significant in relation to the benefit to public health from their continued marketing. FDA has carefully evaluated the risks and benefits of powdered gloves and the risks and benefits of the state of the art, which includes viable non-powdered alternatives that do not

carry any of the risks associated with glove powder, and has determined that the risk of illness or injury posed by powdered gloves is unreasonable and substantial. Further, FDA believes that this ban would likely have minimal economic and shortage impact on the health care industry. Thus, a transition to alternatives in the marketplace should not result in any detriment to public health.

This rule applies to powdered patient examination gloves, powdered surgeon's gloves, and absorbable powder for lubricating a surgeon's glove. This includes all powdered medical gloves except powdered radiographic protection gloves. Because we are not aware of any powdered radiographic protection gloves that are currently on the market, FDA lacks the evidence to determine whether the banning standard would be met for this particular device. The ban does not apply to powder used in the manufacturing process (e.g., former-release powder) of non-powdered gloves, where that powder is not intended to be part of the final finished glove. Finished non-powdered gloves are expected to include no more than trace amounts of residual powder from these processes, and the Agency encourages manufacturers to ensure finished non-powdered gloves have as little powder as possible. In our 2008 Medical Glove Guidance Manual (Ref. 1), we recommended that non-powdered gloves have no more than 2 milligrams (mg) of residual powder and debris per glove, as determined by the Association for Testing and Materials (ASTM) D6124 test method (Ref. 2). The Agency continues to believe this amount is an appropriate maximum level of residual powder. The ban also does not apply to powder intended for use in or on other medical devices, such as condoms. FDA has not seen evidence that powder intended for use in or on other medical devices, such as condoms, presents the same public health risks as that on powdered medical gloves.

B. Summary of the Major Provisions of the Final Rule

In this final rule, FDA is banning the following devices: (1) Powdered surgeon's gloves, (2) powdered patient examination gloves, and (3) absorbable powder for lubricating a surgeon's glove. Because the classification regulations for these device types do not distinguish between powdered and non-powdered versions, FDA is amending the descriptions of these devices in the regulations to specify that the regulations for patient examination and surgeon's gloves will apply only to non-powdered gloves while the powdered version of each type of glove will be added to the listing of banned devices in the regulations.

Many comments requested that FDA revise the scope of the ban to include all NRL gloves. Many comments from industry requested that the proposed effective date be extended beyond 30 days after the date of publication of the final rule. Of the comments that do not support the ban, commenters noted the need for powdered gloves to aid in donning gloves and tactile sense and the reduced risks associated with current powdered gloves that have less powder. The remaining comments are not clearly in support or opposition to the proposal.

C. Legal Authority

Powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove are defined as devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)). Section 516 of the FD&C Act (21 U.S.C. 360f) authorizes FDA to ban a device if it finds, on the basis of all available data and information, that the device presents substantial deception or unreasonable and substantial risks of illness or injury, which cannot be corrected by labeling or a change in labeling. This rule amends 21 CFR 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104. FDA's legal authority to modify §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103,

and 895.104 arises from the device and general administrative provisions of the FD&C Act (21 U.S.C. 352, 360f, 360h, 360i, and 371).

D. Costs and Benefits

The final rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society. Banning powdered glove products is not expected to impose any costs to society, but is expected to reduce the number of adverse events associated with using powdered gloves. The primary public health benefit from adoption of the rule would be the value of the reduction in adverse events associated with using powdered gloves. The Agency estimates maximum total annual net benefits to range between \$26.8 million and \$31.8 million.

II. Background

A. Need for the Regulation/History of the Rulemaking

On March 22, 2016, FDA issued a proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove (81 FR 15173). Section 516(a)(1) of the FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device "presents substantial deception or an unreasonable and substantial risk of illness or injury." For a more detailed discussion of the banning standard, we refer you to the preamble of the proposed rule. FDA issued the proposed regulation because it determined that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling.

The preamble to the proposed rule describes the history of powdered gloves and the citizen petitions received by the Agency that request a ban on powdered gloves. We refer

readers to that preamble for information about the development of the proposed rule. The level and types of risk presented by powdered gloves varies depending on the composition and intended use of the glove. In aggregate, the risks of powdered gloves include severe airway inflammation, hypersensitivity reactions, allergic reactions (including asthma), allergic rhinitis, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue. We refer readers to the preamble of the proposed rule for details on the level and types of risks presented by powdered gloves. The benefits of powdered gloves appear to only include greater ease of donning and doffing, decreased tackiness, and a degree of added comfort, which FDA believes are nominal when compared to the risks posed by these devices.

The state of the art of both surgeon's and patient examination gloves includes non-powdered alternatives that provide similar performance as the various powdered glove types do. That is, there are many non-powdered gloves available that have the same level of protection, dexterity, and performance. Thus, based on a careful evaluation of the risks and benefits of powdered gloves and the risks and benefits of the current state of the art, which includes readily available alternatives that carry none of the risks posed by powdered gloves, FDA has determined that the standard to ban powdered gloves has been met, and that it is appropriate to issue this ban.

Finally, as discussed in the proposed rule, FDA also determined the ban should apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as to devices that would be sold or distributed in the future (see 21 CFR 895.21(d)(7)). This means that powdered gloves currently being used in the marketplace would be subject to this ban and adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)), and thus subject to enforcement action.

B. Summary of Comments to the Proposed Rule

The Agency requested public comments on the proposed rule, and the comment period closed on June 20, 2016. The Agency received approximately 100 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from a cross-section of patients and consumers, medical professionals, device manufacturers, and professional and trade associations. A majority of the comments supported the objectives of the rule in whole or in part, while a minority of the comments opposed the objectives of the rule. Some comments suggested changes to specific elements of the proposed rule or requested clarification of matters discussed in the proposed rule. See Section IV for the description of comments on the proposed rule and FDA's responses.

C. General Overview of the Final Rule

FDA published a proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove, because FDA determined that these devices present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling (81 FR 15173).

In this final rule, FDA is banning the following devices: (1) Powdered surgeon's gloves (21 CFR 878.4460), (2) powdered patient examination gloves (21 CFR 880.6250), and (3) absorbable powder for lubricating a surgeon's glove (21 CFR 878.4480). Because the classification regulations for these device types do not distinguish between powdered and non-powdered versions, FDA is amending the descriptions of these devices in the regulations to specify that the regulations for surgeon's gloves (21 CFR 878.4460) and patient examination gloves (21 CFR 880.6250) will apply only to non-powdered gloves while the powdered version of each type of glove will be added to 21 CFR part 895, subpart B--Listing of Banned Devices.

D. Clarifying Changes to the Rule

While FDA believes that the preamble to the proposed rule was clear that the proposed ban would apply to all powdered surgeon's gloves and all powdered patient examination gloves, in reviewing the terminology used in the proposed additions to 21 CFR part 895, FDA determined that term "synthetic latex" would not cover every type of non-NRL material that is used to manufacture powdered gloves. It was not FDA's intent to limit the ban to only powdered NRL and powdered synthetic latex gloves, and we believe that this intent was clear from the content of the preamble to the proposed rule, which stated that the ban "would apply to all powdered gloves except powdered radiographic protection gloves." As such, FDA has now revised the identification in this final rule to clarify that the ban applies to all powdered surgeon's gloves and powdered patient examination gloves without reference to the type of material from which they are made. Additionally, the identification of non-powdered surgeon's gloves and non-powdered patient examination gloves is also being revised to remove reference to material.

III. Legal Authority

Powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove are defined as medical devices under section 201(h) of the FD&C Act (21 U.S.C. 321). Section 516 of the FD&C Act (21 U.S.C. 360f) authorizes FDA to ban a device if it finds, on the basis of all available data and information, that the device presents substantial deception or unreasonable and substantial risks of illness or injury, which cannot be corrected by labeling or a change in labeling. This rule amends §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104. FDA's legal authority to modify §§ 878.4460, 878.4480, 880.6250, 895.102, 895.103, and 895.104 arises from the device and general administrative provisions of the FD&C Act (21 U.S.C. 352, 360f, 360h, 360i, and 371).

IV. Comments on the Proposed Rule and FDA's Responses

A. Introduction

We received approximately 100 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from a cross-section of patients and consumers, medical professionals, device manufacturers, and professional and trade associations. A majority of the comments supported the objectives of the rule in whole or in part, while a minority of the comments opposed the objectives of the rule. Some comments suggested changes to specific elements of the proposed rule or requested clarification of matters discussed in the proposed rule.

We describe and respond to the comments in section IV.B through E. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Many comments support the proposed ban on powdered patient examination gloves and powdered surgeon's gloves. These comments from individual consumers, health care professionals, academia, and industry highlight several risks of the

continued use of powdered gloves, including, among others, allergic reactions, post-operative adhesions, and delayed wound healing.

(Response 1) FDA agrees with these comments. After further review of all available information and the comments submitted to the proposed rule, FDA has concluded that the public's exposure to the risks of powdered gloves is unreasonable and substantial in relation to the nominal public health benefit derived from the continued marketing of these devices, especially when considering the benefits and risks posed by readily available alternative devices. Therefore, FDA has determined that the standard for a ban on these devices has been met.

C. Description of Comments That Oppose the Regulation and FDA Response

FDA received some comments that oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves for various reasons. We address each of these reasons for opposition in this section. After reviewing these comments, FDA has determined that the standard to ban powdered gloves has been met, and that it is appropriate to issue this ban. We are finalizing the ban with only clarifying changes.

(Comment 2) Comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because of difficulty donning or doffing non-powdered gloves. Two commenters specifically discuss hyperhidrosis with claims that it can add to the difficulty donning and doffing non-powdered gloves. One commenter has asserted that double-gloving is more difficult when using non-powdered gloves.

(Response 2) As described in the preamble of the proposed rule, we have concluded that the benefit of ease of donning or doffing powdered gloves is generally nominal (Ref. 3) in comparison to the risks posed by the continued marketing of powdered gloves, which, among others, include severe airway inflammation, hypersensitivity reactions, and allergic reactions

(including asthma). Also, as noted in the proposed rule, a study of various brands of powdered and non-powdered NRL gloves by Cote et al. found that there are non-powdered latex gloves that are easily donned with wet or dry hands with relatively low force compared to the forces required to don powdered latex examination gloves (Ref. 3). Thus, FDA has considered ease of donning and doffing as a benefit as it applies within the banning standard, and has determined that the standard is met.

(Comment 3) Comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because of difficulty donning non-powdered gloves, leading to greater propensity of non-powdered gloves to tear. Some of these comments express concern that the reduced ability to separate the opening of a non-powdered glove or the greater propensity of non-powdered gloves to tear could potentially lead to a higher degree of contamination and post-procedure infections.

(Response 3) FDA disagrees with the assertion that non-powdered gloves have a higher propensity to tear and thus disagrees that use of non-powdered gloves presents a greater risk of contamination, post-procedure infections, or exposure of the user to blood. FDA does not believe there is compelling evidence to support the assertion that non-powdered gloves have a higher propensity to tear. Korniewicz, et al., determined that the presence of powder did not affect the durability of gloves or enhance glove donning (Ref. 4). Although Kerr, et al., identified a statistically significant difference in the durability of non-powdered vinyl gloves compared to powdered vinyl gloves, this difference may be attributed to glove type, manufacturer, and the fingernail length of users rather than the presence or absence of powder (Ref. 5). This study also found that vinyl gloves in general are less durable and have a greater propensity to tear compared to nitrile, neoprene, and latex gloves. Furthermore, as discussed in

the response to comment 4, several studies have found that alternatives to non-powdered NRL gloves, such as nitrile and neoprene gloves, offer the same level of protection against contamination and exposure to blood as powdered NRL gloves (Refs. 5, 6, 7, 8, 9, and 10). Therefore, FDA has determined that suitable alternatives to powdered gloves are readily available in the marketplace.

(Comment 4) Commenters oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves because the fit of powdered gloves is more comfortable than non-powdered gloves. Some of these comments assert that the reduced fit of non-powdered gloves inhibits the tactile sensation necessary to perform medical procedures.

(Response 4) FDA disagrees with the assertion that non-powdered gloves inhibit the tactile sensation necessary to perform medical procedures. The ban does not include non-powdered NRL gloves, which offer the same performance characteristics of powdered NRL gloves, and several studies have found that alternatives, such as nitrile and neoprene gloves, offer the same level of protection, dexterity, and performance as NRL gloves (Refs. 5, 6, 7, 8, 9, and 10). Furthermore, the numerous risks posed by the continued marketing of powdered gloves outweigh the benefit of whatever additional level of comfort is provided from using powdered gloves instead of the non-powdered alternatives that carry none of these risks.

(Comment 5) Some comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, citing a lack of scientific evidence that gloves with reduced powder content, as those in use today, have the same risks as previously used gloves that had higher powder content.

(Response 5) FDA agrees that the maximum residual level of powder on powdered gloves is less than earlier types of powdered gloves. Historically, powdered medical gloves

contained powder levels ranging from 50 to over 400 mg of powder per glove. Effective in 2002, the ASTM International recommended limits on powder levels is 15 mg per square decimeter for surgical gloves (ASTM D3577-2001) (Ref. 11) and 10 mg per square decimeter for patient examination gloves (ASTM D3578) (Ref. 12). As a result, FDA believes that gloves in use after 2002 follow these recommended limits and generally have lower powder content than earlier types of powdered gloves. Even so, several studies indicate that gloves with reduced powder levels continue to present unreasonable and substantial risks to patients and health care workers. For instance, a study conducted on the incidence of skin reactions for Greek endodontists from 2006 to 2012 found that glove powder accounted for the majority of skin reactions, and the replacement of powdered NRL gloves with non-powdered gloves resolved the majority of the adverse reactions (Ref. 13). Similarly, the risks of powdered gloves persist in non-clinical studies using gloves with reduced powder content, as demonstrated by the 2013 finding that surgeries performed with powdered gloves increased the number, density, and fibrotic properties of peritoneal adhesions in rats compared with surgeries performed with non-powdered gloves (Ref. 14). Also, the reduction in cases of NRL-induced occupational contact urticaria coincided with French hospitals transitioning to non-powdered gloves after 2004-2005 (Ref. 13). Finally, FDA is not aware of any report in the literature that supports the assertion that currently marketed powdered gloves with lower powder content reduce the risks presented by powdered gloves (Ref. 15). In summary, FDA concludes that the risks of powder continue to be unreasonable and substantial for currently marketed powdered gloves despite lower powder content than previous generations of powdered gloves.

(Comment 6) Two comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the commenters believe a warning on the risks of powdered gloves is sufficient to mitigate the risks posed by these devices.

(Response 6) As described in Section IV of the proposed rule, FDA has determined that no change in labeling could correct the risk of illness or injury presented by the continued use of these devices. Powdered gloves have additional or increased risks to health compared to non-powdered gloves related to the spread of powder, and the fact that powder-transported contaminants such as NRL allergens can become aerosolized. Exposure to powder or latex allergens presents significant risks to health care workers and patients when inhaled or when exposed to internal tissue during oral, vaginal, gynecological, and rectal exams. Although labeling can raise awareness of these risks, we conclude that labeling cannot effectively mitigate these risks because it cannot prohibit the spread of glove powder or powder-transported contaminants. In addition, an important aspect of these devices is their ability to affect persons other than the individual who decides to wear or use them. For example, patients often do not know the type of gloves being worn by the health care professional treating them, but are still exposed to the potential dangers. Similarly, glove powder's ability to aerosolize and carry NRL proteins exposes individuals to harm via inhalation or surface contact. Thus, some of the risks posed by glove powder can impact persons completely unaware or unassociated with its employment and without the opportunity to consider the devices' labeling. Because of this inherent quality, adequate directions for use or warnings cannot be written that would provide reasonable assurance of the safe and effective use of these devices for all persons that might come in contact with them.

Due to the ability of powder to affect people who would not have an opportunity to read warning labels, and because potential warning labels would raise awareness of the risks, but would not eliminate the risks posed by glove powder, FDA has determined no label or warning can correct the risks posed by these devices.

(Comment 7) One comment opposes the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the solvent used to remove powder during the manufacture of non-powdered gloves may cause adverse reactions to the glove user.

(Response 7) FDA is not aware of any report in the literature that supports the assertion of widespread adverse reactions to solvent used in the manufacturing process. Non-powdered patient examination and surgeon's gloves require premarket notification (510(k)) submissions prior to marketing. During the review of these submissions, FDA evaluates the final finished glove, including manufacturing solvents that are present on the final glove. FDA recommends that manufacturers conduct and submit skin irritation and dermal sensitization studies in these submissions to evaluate potential issues with components, including manufacturing solvents (Ref. 1). Although individual hypersensitivity reactions to different materials may occur, FDA has been unable to find evidence in the literature of hypersensitivity to typical glove manufacturing materials other than glove powder or NRL. However, Palosuo, et al., reports that the use of hand sanitizers containing isopropyl alcohol prior to donning gloves could cause dermatitis reaction if the gloves are donned before the alcohol dries (Ref. 16). The occurrence of this reaction is unrelated to the manufacture of non-powdered gloves and unrelated to the use of non-powdered gloves as an alternative to powdered gloves. Given the lack of evidence of adverse reactions to solvents used in the manufacturing of non-powdered gloves, and the

established evidence demonstrating the risks of powdered glove use, FDA continues to believe that powdered gloves and glove powder meet the banning standard.

(Comment 8) Several comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves due to the expectation that users will ultimately have to pay more for medical gloves once the ban is finalized, because the cost of non-powdered gloves is currently higher than the cost of powdered gloves.

(Response 8) We do not find any evidence to support the claims that current prices of non-powdered gloves are significantly higher than powdered gloves. As we stated in the preliminary regulatory impact analysis (PRIA), extensive searches of glove distributor pricing indicate that non-powdered gloves have become as affordable as powdered gloves. Our searches also revealed that the market is saturated with alternatives to powdered gloves, resulting in downward pressure on the prices of non-powdered gloves. In addition, the share of powdered medical gloves sales has been declining since at least 2000 while total sales of all disposable medical gloves have increased (Ref. 17). We would not expect this trend to be occurring without regulatory action if users of disposable medical gloves faced significantly higher prices for switching to non-powdered gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 9) We received one comment that disagrees with our determination that the availability of examination and surgical gloves would not be reduced.

(Response 9) We do not find any evidence to support these claims. As we stated in the PRIA, research shows only 7 percent of total sales of examination and surgical gloves to medical workers were projected to be from powdered gloves in 2010 (Ref. 17). Global Industry Analysts (GIA) projected the share of powdered disposable medical gloves sales to decrease to 2 percent

in 2015, while total sales of all disposable medical gloves continue to increase (Ref. 17). We would not expect this trend to be occurring without regulatory action if there were a reduction in the availability of disposable examination and surgical gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 10) Commenters suggest there would be a loss in consumer utility due to the preference some medical workers may have for powdered gloves due to comfort and ease of use.

(Response 10) We stated in the PRIA that the remaining 7 percent continuing to use these powdered gloves may experience utility loss from the removal of powdered gloves from the market (Ref. 17). The potential loss in consumer utility would be due to the perceived loss in comfort from powdered gloves users switching to non-powdered gloves. However, as the GIA report shows, there has been a downward trend in total sales of powdered gloves since at least the year 2000 while total sales of all disposable medical gloves has increased (Ref. 17). We would not expect this trend to be occurring without regulatory action if the loss in consumer utility to current medical workers were substantial. Korniewicz et al. reported no loss in consumer satisfaction in a sample of operating room staff switching to non-powdered surgical gloves (Ref. 4). We have not estimated this potential burden, but the evidence described here suggests that any burden would not be substantial. Further, even having considered that some degree of consumer comfort may be lost by banning powdered gloves, FDA continues to believe that this benefit is considerably outweighed by the numerous risks posed by powdered gloves.

(Comment 11) One comment opposes the proposed ban on powdered patient examination gloves and powdered surgeon's gloves, because the risks identified for powdered gloves are due to contaminants, such as pesticides and herbicides, in the powder that would not be present if the powder were manufactured in the United States.

(Response 11) FDA disagrees with the assertion that contaminated powder is the source of the risks identified for powdered gloves. FDA's proposal to ban powdered gloves and glove powder is based on various studies on the risks of powdered gloves due to the properties of the powder itself. Powdered gloves have additional or increased risks to health compared to non-powdered gloves. For example, powder on NRL gloves can aerosolize latex allergens, resulting in sensitization to latex and allergic reactions. Latex sensitization and allergic reactions are unrelated to any potential presence of manufacturing contaminants, such as pesticides and herbicides. Additional risks of powdered gloves include severe airway inflammation, conjunctivitis, dyspnea, as well as granuloma and adhesion formation when exposed to internal tissue. FDA's assessment of the available literature and information indicates that these risks are attributable to the powder itself, as opposed to any potential presence of manufacturing contaminants, such as pesticides and herbicides.

In addition, the powder used on powdered gloves is required to comply with FDA's Quality System regulation, which includes requirements for quality and inspection for the final finished gloves that protect against the introduction of contaminated devices into commerce. Among other requirements, device manufacturers must establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality (21 CFR 820.70(e)). FDA's Quality System regulation applies to gloves and glove powder sold in the United States, regardless of the manufacturing location.

D. Description of Comments on Scope of Ban and FDA Response

FDA received several comments requesting revision of the scope of the ban. The scope of the proposed ban includes powdered surgeon's gloves, powdered patient examination gloves,

and absorbable powder for lubricating a surgeon's glove. The glove types include all powdered patient examination and surgeon's gloves, including NRL and synthetic latex gloves. In the following paragraphs, we discuss and respond to comments requesting revision of the scope of the ban. We are finalizing the ban without change to the scope, but clarifying that all powdered patient examination gloves and powder surgical gloves are banned, regardless of the material from which they are made.

(Comment 12) Several comments identify risks that result from the use of powdered and non-powdered NRL gloves. These comments request FDA to extend the ban to all NRL gloves, both powdered and non-powdered.

(Response 12) Unlike with powdered latex gloves, which have the ability to aerosolize glove powder and carry allergenic proteins, FDA believes the risk of allergic reaction to non-powdered NRL gloves, which affects the user and patients in direct contact with the glove, is adequately mitigated through already-required labeling that alerts users to this risk. NRL gloves must include a statement to alert users to the risk of allergic reactions caused by NRL (21 CFR 801.437). Further, several studies have indicated that the use of non-powdered NRL gloves reduces the risk of sensitization to allergenic NRL proteins and the number of allergic reactions experienced by those who are already sensitized (Refs. 18, 19, and 20). FDA believes that these study results, when considered alongside the risk mitigation that follows from FDA's required labeling for NRL products, demonstrates that non-powdered latex gloves can be safely used with appropriate caution for latex-sensitive patients and health care workers. Therefore, FDA has determined not to ban the use of all NRL gloves.

(Comment 13) Several comments raise the issue of life threatening latex allergy events that result from various uses of NRL gloves including food preparation and food service.

Several of these comments assert that the Agency should broaden the scope of the ban to cover all NRL gloves for all uses including food preparation and food service.

(Response 13) We have concluded that it is not appropriate to address a proposal to ban gloves used for food preparation because these gloves do not meet the definition of a device under section 201(h) of the FD&C Act and are thus not subject to section 516 of the FD&C Act (21 U.S.C. 360f), which provides the statutory authority to ban devices within FDA's authority to regulate such products.

(Comment 14) One comment asserts that the ban on powdered gloves should not apply to dental practice, because the risks are not applicable to dental practice.

(Response 14) FDA disagrees with the assertion that the risks of powdered gloves are not applicable to dental practice. Dentists and dental patients face the same risks as other medical practices in terms of the potential for powder exposure to open cavities or open wounds, and for powder, if used with NRL gloves, to carry protein allergens. Several studies documenting the risks of powdered gloves in dental practices have been conducted, including Saary, et al., which identified that changing to low-protein and non-powdered NRL gloves reduced NRL allergy in dental students (Ref. 18). In addition, Charous et al., reported in 2000 that a dental office was able to reduce airborne NRL antigen levels to undetectable levels with the exclusive use of non-powdered NRL gloves, permitting a highly sensitized staff member to continue to work there (Ref. 21). These studies, among others (Refs. 13 and 22), indicate that the risks of powdered medical gloves apply to dental practice. Therefore, FDA has determined that the scope of the ban on powdered medical gloves should continue to include powdered gloves used in dental practice.

E. Description of Other Specific Comments and FDA Response

Many comments made specific remarks requesting clarification or revision to the proposed rule. In the following paragraphs, we discuss and respond to such specific comments.

(Comment 15) A number of comments request extension of the effective date of the ban. The proposed rule included a proposed effective date of 30 days after publication of the final rule for all devices, including those already in commercial distribution. The comments suggest a range of effective dates of 90 days to 18 months after publication of the final rule and assert that a longer transition period is necessary to allow existing inventory to flow through the supply chain to providers and patients.

(Response 15) FDA is not extending the effective date of the ban for devices already in commercial distribution. We have concluded that powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. The continued marketing of these devices beyond the 30 day effective date would allow for the continued sale and purchase of devices that FDA has determined present an unreasonable and substantial risk to patients and health care workers. Therefore, FDA does not believe that it is in the best interest of the public health to extend the effective date for devices already in commercial distribution. In order to minimize the risk of continued exposure of health care workers and patients to these devices, the effective date for devices remains 30 days after the date of publication of this final rule.

(Comment 16) One comment requests that FDA not extend the effective date of the ban to allow companies to deplete their inventory of the devices.

(Response 16) As described in the response to comment 15, FDA agrees that it is in the best interest of the public health to not extend the effective date of the ban for devices already in

commercial distribution. Therefore, the effective date of the ban for devices already in commercial distribution remains at 30 days after the date of publication of the final rule.

(Comment 17) A few comments request recommendations on the means of disposal or recycling of powdered gloves.

(Response 17) FDA recommends that unused inventories of powdered medical gloves remaining at domestic manufacturing and distribution locations be disposed of in accordance with standard industry practices. Unused supplies at hospitals, outpatient centers, clinics, medical and dental offices, other service delivery points (nursing homes, etc.), and in the possession of end users, will need to be disposed of according to established procedures of the local community's solid waste management system. Established procedures for these materials typically involve disposal in landfills or incineration. FDA has concluded that this final rule will not have a significant impact on the human environment. (See Section VII. Analysis of Environmental Impact.)

(Comment 18) One comment requests clarification on whether after the effective date of the ban the Agency will permit a manufacturer to export powdered medical gloves that are already physically located at distribution centers in the United States.

(Response 18) After the effective date of this final rule, manufacturers will not be allowed to import powdered medical gloves. However, while powdered medical gloves will be banned in the United States on the effective date of this final rule, manufacturers may export existing inventory of powdered gloves to a foreign country if the device complies with the laws of that country and has valid marketing authorization by the appropriate authority, as described in section 802 of the FD&C Act (21 U.S.C. 382)). If eligible for export under section 802 of the FD&C Act, a device intended for export will not be deemed adulterated or misbranded if it

- (A) accords to the specifications of the foreign purchaser,
- (B) is not in conflict with the laws of the country to which it is intended for export,
- (C) is labeled on the outside of the shipping package that it is intended for export, and
- (D) is not sold or offered for sale in domestic commerce.

V. Effective Date

This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The effective date of this rule applies to devices already in commercial distribution and those already sold to the ultimate user, as well as to devices that would be sold or distributed in the future. All powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's gloves must be removed from the market upon the effective date of this final rule. Section 501(g) of the FD&C Act (21 U.S.C. 351(g)) deems a device to be adulterated if it is a banned device.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule imposes no new burdens, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule prohibits marketing of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating surgeon's gloves. The rule does not cover or include powdered radiographic gloves.

The final rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society. Banning powdered glove products is not expected to impose any costs to society. Extensive searches of glove distributor pricing indicate that improvements to non-powdered gloves have made these products as affordable as powdered gloves. The ban is expected to reduce the adverse events associated with using powdered gloves. The Agency estimates maximum total annual net benefits to range between \$26.8 million and \$31.8 million. The present discounted value of the estimated benefits over 10 years ranges from \$228.9 million

to \$270.8 million at a 3 percent discount rate and from \$188.5 million to \$223 million at a 7 percent discount rate.

FDA has examined the economic implications of the rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. This rule will not impose any new burdens on small entities, and thus will not impose a significant economic impact on a substantial number of small entities.

The full discussion of the economic impacts of the rule, which includes a list of changes made in the final regulatory impact analysis, in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act is available at <https://www.regulations.gov> under the docket number (FDA-2015-N-5017) for this rule and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm#> (Ref. 23).

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this final rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of disposal of unused powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove that will need to be handled after the rule is finalized.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a

significant impact on the environment. The EA considered environmental impacts related to landfill and incineration of solid waste at municipal solid waste (MSW) facilities nationwide. The selected action, if finalized, will result in an initial batch disposal of unused powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove from user facilities to MSW facilities nationwide, followed by a rapid decrease in the rate of disposal of these devices, as supplies are depleted. The selected action does not change the ultimate disposition of these devices but expedites their rate of disposal and ceases future production. Overall, given the limited number of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove, currently in commercial distribution, the selected action is expected to have no significant impact on MSW and landfill facilities and the environment in affected communities.

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding, contained in an EA, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday (Ref. 24).

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, FDA is not required to seek clearance by Office of Management and Budget under the Paperwork Reduction Act of 1995.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

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24. FDA, "Finding of No Significant Impact (FONSI) and Environmental Analysis for Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove."

List of Subjects

21 CFR Parts 878 and 880

Medical devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 878, 880, and 895 are amended as follows:

PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Amend § 878.4460 by revising the section heading and paragraph (a) to read as follows:

§ 878.4460 Non-powdered surgeon's glove.

(a) Identification. A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

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§ 878.4480 [Removed]

3. Remove § 878.4480.

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES

4. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

5. Amend § 880.6250 by revising the section heading and paragraph (a) to read as follows:

§ 880.6250 Non-powdered patient examination glove.

(a) Identification. A non-powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

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PART 895--BANNED DEVICES

6. The authority citation for part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

7. Add § 895.102 to read as follows:

§ 895.102 Powdered surgeon's glove.

(a) Identification. A powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

8. Add § 895.103 to read as follows:

§ 895.103 Powdered patient examination glove.

(a) Identification. A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

9. Add § 895.104 to read as follows:

§ 895.104 Absorbable powder for lubricating a surgeon's glove.

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

Dated: December 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-30382 Filed: 12/16/2016 8:45 am; Publication Date: 12/19/2016]