(h) Subject

Joint Aircraft Service Component (JASC) Code: 6510, Tail Rotor Drive Shaft.

Issued in Fort Worth, Texas, on March 15, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–06373 Filed 3–21–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 74

[Docket No. FDA–2016–F–0821]

Milton W. Chu, M.D.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Milton W. Chu, M.D., proposing that the color additive regulations be amended to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper as orientation marks for intraocular lenses.

DATES: The color additive petition was filed on February 19, 2016.

FOR FURTHER INFORMATION CONTACT: Laura Dye, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1275.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 6C0305), submitted by Milton W. Chu, M.D., 5800 Santa Rosa Rd., Suite 111, Camarillo, CA 93012. The petition proposes to amend the color additive regulations in § 73.3126 *Titanium dioxide* (21 CFR 73.3126) and § 74.3045 *[Phthalocyaninato (2-)] copper* (21 CFR 74.3045) to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper as orientation marks for intraocular lenses.

We have determined under 21 CFR 25.32(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 17, 2016.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2016–06397 Filed 3–21–16; 8:45 am]

BILLING CODE 4164–01–P

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; Proposal To Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed 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 proposing these devices be banned.

DATES: Submit either electronic or written comments by June 20, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–5017 for ''Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Claverie-Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2508, Silver Spring, MD 20993, 301–796–6298, email: *elizabeth.claverie@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The Medical Device Amendments of 1976 (Pub. L. 94–295) (the amendments), amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321 *et seq.*), became law on May 28, 1976. Among other provisions, the amendments added section 516 to the FD&C Act (21 U.S.C. 360f), which authorizes FDA to ban by regulation any device intended for human use if FDA finds, based on all available data and information, that such device presents a ''substantial deception'' or an ''unreasonable and substantial risk of illness or injury,'' which cannot be, or has not been, corrected or eliminated by labeling or a change in labeling.

FDA is proposing to ban powdered surgeon's gloves (21 CFR 878.4460), powdered patient examination gloves (21 CFR 880.6250), and absorbable powder for lubricating a surgeon's glove (21 CFR 878.4480). Non-powdered gloves are not included in this ban. In order to clarify this distinction, we are proposing to amend the descriptions of these devices in the regulations to specify that, if the ban were to be finalized, these regulations would apply only to non-powdered gloves. FDA's conclusions, which are discussed in this document, are based on an evaluation of all available data and information known to the Agency. However, to the extent that there is additional information that we should consider regarding the risks and benefits of powdered gloves, comments should be submitted as described previously.

The proposed rule would apply to all powdered gloves except powdered radiographic protection gloves. FDA has determined that the banning standard does not apply to this type of glove. In addition, we are not aware of any powdered radiographic protection gloves that are currently on the market. The proposed ban would 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 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, but may reevaluate this amount if more information becomes available. The proposed ban would also 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.

A. History of Powdered Gloves and Their Regulation

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. The first lubricant powder used to aid in surgical glove donning, introduced in the late nineteenth century, was composed of *Lycopodium* spores (club moss spores) or ground pine pollen (Refs. 3 and 4). By the 1930s, Lycopodium powder was recognized to cause wound granulomas and adhesion formation and was replaced by talcum powder (chemically hydrous magnesium silicate), a nonabsorbable lubricant powder. In the 1940s, talcum powder (talc) was also recognized to be a cause of postoperative adhesions and granuloma formation. In 1947, modified cornstarch powder was introduced as an absorbable and non-irritating glove powder, and it largely replaced talc as a donning lubricant for surgical gloves by the 1970s. Cornstarch is currently the most commonly used type of absorbable glove powder.

In the 1980s, preventing the transmission of acquired immunodeficiency syndrome (AIDS) became a major public health concern. The Centers for Disease Control and Prevention (CDC) recommended that health care workers use appropriate barrier precautions to prevent exposure to the human immunodeficiency virus (HIV) and other bloodborne pathogens. Responding to heightened concerns about cross-contamination between patients and health care workers, in the **Federal Register** of January 13, 1989 (54 FR 1602), FDA revoked the exemption for patient examination gloves from certain current good manufacturing practice requirements in order to ensure that manufacturers provide an acceptable manufacturing quality level. FDA similarly revoked the exemption from premarket notification

requirements for patient examination gloves.

On December 12, 1990, FDA published regulations describing certain circumstances under which surgeon's and patient examination gloves would be considered adulterated (55 FR 51254). The regulations established the sampling plans and test methods for glove leakage defects that we would use to determine whether gloves were adulterated (see 21 CFR 800.20). These sampling plans and test methods were further updated in 2006 (December 19, 2006, 71 FR 75865 at 75876). Subsequently, we initiated inspections of glove manufacturers to ensure conformance with the acceptable quality levels identified in the regulation.

In 1997, FDA issued its Medical Glove Powder Report (Ref. 5), which described the risks presented by glove powder and the state of the medical glove market at that time. We reviewed the clinical and experimental data on the risks and adverse events associated with the use of powder on surgical and medical gloves available at that time in the medical literature. We also reviewed the information in our MedWatch database on the adverse events associated with the use of powdered gloves. In addition, the Agency reviewed the commercial information available at that time on sources for medical gloves, relative numbers and types of gloves, and the costs of different glove types. FDA found that glove powder could cause inflammation and granulomas, and that aerosolized glove powder on natural rubber latex (NRL) gloves can carry allergenic proteins that have the potential to cause respiratory allergic reactions.

Even though the Agency was aware of certain health risks presented by glove powder, based on the totality of information available in 1997, the Agency opted not to initiate a ban. At the time, use of chlorination was the most common alternative to powder for the purpose of lubricating NRL surfaces. However, the chlorination process was recognized to cause physical damage to gloves and to alter the physical properties of treated gloves if not performed properly (Ref. 5). In 1997, FDA was concerned that widespread use of glove chlorination would compromise some of the mechanical and physical properties of gloves including shelf life, grip, and in-use durability, since these were widely recognized risks of poorly managed chlorination processes. Polymer coatings to replace glove powder for glove lubrication had been developed but, because of their increased cost, were not yet in widespread use at the time. The report concluded that banning powdered gloves in 1997 would cause a market shortage of medical gloves, which could result in inferior glove products and increased costs to the U.S. health care system due to a lack of immediate availability of suitable alternatives.

We identified two options in 1997: (1) Provide adequate information for the consumer to make an informed decision by, among other things, requiring that the amount of water-soluble NRL proteins and the amount of glove powder present in powdered gloves be stated on the product label and establishing upper limits for the amount of these substances allowed in gloves, or (2) initiate the process to ban glove powder at some predetermined time in the future and require manufacturers to convert to powder-free production or provide safety data, including foreign body and airborne allergen concerns, by a certain date.

At that time, the Agency determined that the first option was preferable and issued the draft guidance entitled ''Draft Guidance for Industry and FDA Staff: Medical Glove Guidance Manual'' on July 30, 1999 (Ref. 6). In addition to other changes, including the natural rubber latex caution statement for gloves made of NRL, this document advised industry that FDA recognized the newly issued consensus standard ASTM D6124, ''Standard Test Method for Residual Powder on Medical Gloves,'' which established an accepted method to measure residual powder or debris on medical gloves (Ref. 2). In the draft guidance, we recommended that medical gloves have no more than 2 mg of residual powder or debris per glove in order to label that glove as ''powder-free.'' Since 1999, gloves with low amounts of residual powder after manufacturing have been referred to as ''powder-free'' or ''powderless.'' Such gloves may have residual powder from the manufacturing process removed by washing and chlorination, and they may be coated with a polymer to aid donning. For comparison, powdered medical gloves contain approximately 120 to 400 mg of residual particulates, mold release, and donning powder.

In addition to the draft guidance issued in 1999, in the same issue of the **Federal Register**, FDA proposed regulations to reclassify all surgeon's and patient examination gloves as class II medical devices (July 30, 1999, 64 FR 41710). While the proposed rule was never finalized, the preamble provided FDA's rationale for choosing not to initiate a ban for powdered surgeon's and patient examination gloves at the time. We explained that: (1) A ban would not address exposure to natural latex allergens from medical gloves with high levels of natural latex proteins; (2) a ban of powdered gloves might compromise the availability of high quality medical gloves; and (3) a ban of powdered gloves might greatly increase annual costs by almost as much as $64 million over the alternative approach proposed by FDA in the ''Draft Guidance for Industry and FDA Staff: Medical Glove Guidance Manual.''

FDA did not finalize the 1999 Draft Guidance. The Draft Guidance was withdrawn when we issued our ''Guidance for Industry and FDA Staff—Medical Glove Guidance Manual,'' on January 22, 2008 (Ref. 1). Recognition and use of ASTM D6124 to reduce the powder burden on medical gloves continued in the revised guidance. Since we issued the draft guidance in 1999, the number of adverse events reported to FDA related to glove use and the number of powdered glove devices seeking premarket clearance have decreased.

B. Citizen Petitions

FDA has received several citizen petitions regarding the use of glove powder. In 1998, a citizen petition was submitted by Public Citizen requesting that FDA ban the use of cornstarch powder in the manufacture of latex surgeon's and patient examination gloves (see Docket No. FDA–2008–P–0531). While there was scientific evidence in 1998 that indicated that the use of glove powder was associated with negative health consequences (partly due to the ability of glove powder to facilitate sensitization of health care workers to NRL and partly due to adverse effects due only to contact with glove powder), as discussed previously, quality concerns, the lack of suitable alternatives, and costs weighed against FDA initiating the process to remove powdered gloves from the market. Moreover, the impact of reductions in the amount of NRL protein used in gloves and in the amount of powder added to gloves, which were being done as means to mitigate the risk of health care worker sensitization to NRL, had not yet been studied for a reasonable length of time. As a result of these considerations, we did not grant the 1998 petition to ban the use of glove powder.

Approximately a decade later, between 2008 and 2011, FDA received three petitions requesting, among other things, that the Agency ban the use of cornstarch powder on NRL and synthetic latex surgical and examination gloves (FDA–2008–P–0531–0001, FDA–2009–P–0117–0001, and FDA–2011–P–

0331–0001). These petitions prompted us to evaluate new data on the risks of using powdered gloves, to consider new information regarding the current availability and costs of alternatives to glove powder for glove lubrication, and to reassess the frequency of use of powdered medical gloves. As a result of these petitions, FDA published in 2011 in the **Federal Register** a document requesting comments related to the risks and benefits of powdered gloves (February 7, 2011, 76 FR 6684; FDA–2011–N–0027). In addition, although we believed that additional labeling would not correct or eliminate the risks associated with glove powder, we decided that it was important to inform consumers about the risks of powdered gloves while FDA assessed whether glove powder had benefits that might affect the determination of whether or not a ban on the devices was appropriate at this time. Accordingly, on February 7, 2011, FDA issued the draft guidance entitled ''Draft Guidance for Industry and FDA Staff: Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder,'' which proposed a general voluntary warning for powdered glove devices, regardless of whether the devices were surgeon's gloves or patient examination gloves (Ref. 7). As we reviewed the comments received on the benefits and risks of glove powder, we determined that a ban on powdered gloves is appropriate and determined not to finalize the draft guidance. This draft guidance was withdrawn on May 6, 2015 (80 FR 26059) as part of a mass withdrawal effort to remove draft guidance documents issued before 2014 that have not been finalized. When final, this rule will address the risks of powdered gloves that were addressed in the draft guidance.

C. Scope of the Ban

FDA is proposing to ban 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 proposing to amend the descriptions of these devices in the regulations to specify that, if this proposed ban is finalized, these regulations will apply only to non-powdered gloves while the powdered version of each type of glove will be added to 21 CFR 895 Subpart B—Listing of Banned Devices.

D. Legal Standard

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.'' A banned device is adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)).

In determining whether a deception or risk of illness or injury is ''substantial,'' FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing (see 21 CFR 895.21(a)(1)). Although FDA's device banning regulations do not define ''unreasonable risk,'' in the preamble to the final rule promulgating 21 CFR part 895, we explained that, with respect to ''unreasonable risk,'' it ''will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users'' (44 FR 29214 at 29215, May 18, 1979). The state of the art with respect to this proposed rule relates to current technical and scientific knowledge and medical practice as it pertains to the various medical gloves that are used when treating patients.

Thus, in determining whether a device presents an ''unreasonable and substantial risk of illness or injury,'' FDA analyzes the risks and the benefits the device poses to patients and, in the case of powdered gloves, other individuals who come in contact with these devices, by comparing those risks and benefits to the risks and benefits posed by alternative devices and/or treatments being used in current medical practice. Actual proof of illness or injury is not required; we need only find that a device presents the requisite degree of risk on the basis of all available data and information (H. Rep. 94–853 at 19; 44 FR 29215).

Whenever FDA finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device (see 21 CFR 895.20). If FDA determines that the risk can be corrected through labeling, FDA will notify the responsible person of the required labeling or change in labeling necessary to eliminate or correct such risk (see 21 CFR 895.25).

Section 895.21(d) requires this proposed rule to summarize: (1) The Agency's findings regarding substantial deception or the unreasonable and substantial risk of illness or injury; (2) the reasons why FDA initiated the proceeding; (3) the evaluation of the data and information FDA obtained under provisions (other than section 516) of the FD&C Act, as well as information submitted by the device manufacturer, distributer, or importer, or any other interested party; (4) the consultation with the classification panel; (5) the determination that labeling, or a change in labeling, cannot correct or eliminate the deception or risk; (6) the determination of whether, and the reasons why, the ban should apply to devices already in commercial distribution, sold to ultimate users, or both; and (7) any other data and information that FDA believes are pertinent to the proceeding.

We have grouped some of these together within broader categories and address them in the following order:

- Evaluation of data and information regarding glove powder, including data and information FDA obtained under provisions other than section 516 of the FD&C Act, information submitted by the device manufacturer and other interested parties, the consultation with the classification panel, and other data and information that FDA believes are pertinent to the proceeding, with respect to:
  - Benefits
  - Risks
  - State of the Art
- The reasons FDA initiated the proceeding, our determination that glove powder presents an unreasonable and substantial risk of illness or injury (FDA has not made a finding regarding substantial deception);
- FDA's determination that labeling, or a change in labeling, cannot correct or eliminate the risk; and
- FDA's determination that the ban applies to devices already in commercial distribution and sold to ultimate users, and the reasons for this determination.

II. Evaluation of Data and Information Regarding Glove Powder

A thorough review of the information that has become available since FDA issued the Medical Glove Powder Report in 1997 (Ref. 5) 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. As discussed in the paragraphs that follow, FDA has concluded that the risks posed by powdered gloves, including health care worker and patient sensitization to 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, outweigh the benefits that these devices pose to patients. FDA's position is bolstered when the state of the art for medical gloves is considered, which includes viable non-powdered alternatives that do not carry any of the risks associated with glove powder. Further, unlike when this decision was considered previously, 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.

In reaching the conclusions that form the basis for this proposed rule, FDA considered evidence from multiple sources. FDA re-examined the 1997 Report on Medical Glove Powder (Ref. 5) along with its scientific and clinical literature references, its analysis of reported adverse events due to the use of gloves, and its analysis of glove market availability (Ref. 5). In addition, we performed a more contemporary analysis of relevant scientific literature and of adverse events related to medical glove use from 1992 through 2014 and obtained new market availability data on medical glove use by type. We also reviewed the information contained in related citizen petitions, as well as the comments associated with the petitions. Further, the Agency reviewed the public statements and actions of other U.S. government Agencies, U.S. health care organizations, and of foreign governments concerning powdered natural rubber latex gloves.

The sections that follow discuss the information that FDA evaluated as part of the decision to propose this ban. Sections II.A and II.B provide a concise summary of the benefits and risks that FDA believes are posed by the use of powdered gloves. Section II.C provides a discussion on the state of the art as it pertains to medical gloves. Sections II.D, II.E, and II.F provide detailed discussions of the scientific literature, actions of other regulatory and professional organizations, and adverse event reports that formed the basis of the summaries in sections II.A and II.B.

A. Summary of Benefits for Devices That FDA Is Proposing To Ban

To help determine whether powdered gloves present an unreasonable and substantial risk of illness or injury, FDA issued a notice in the **Federal Register** requesting public input on the risks and benefits of powdered gloves (February 7, 2011, 76 FR 6684; FDA–2011–N–0027). FDA received nearly 300 comments to the docket, the large majority of which addressed the continuing risks associated with the use of powdered gloves, which are discussed later in this document. Comparatively, very few comments addressed the benefits of gloves that are powdered, and the benefits that were addressed were minimal. The primary benefits described in the comments were almost entirely related to greater ease of donning and doffing gloves and decreased tackiness of gloves packaged together. These benefits apply to both powdered surgeon's gloves and powdered patient examination gloves. The benefits of absorbable powder for lubricating a surgeon's glove derive from the benefits of powdered surgeon's gloves, which include ease of donning and doffing gloves and decreased tackiness.

Some studies have reported that alternatives to powdered gloves, such as vinyl gloves, may not provide as good of dexterity and biological impermeability as NRL gloves (Ref. 8). However, this proposed 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 (Ref. 9 to 14). Thus, the only benefits to using powdered gloves that FDA has been able to identify is a greater ease of donning and doffing and decreased tackiness of gloves packaged together.

B. Summary of Risks for Devices That FDA Is Proposing To Ban

Although some risks of these devices are similar for all glove types, the level and types of risks presented by powdered gloves can vary depending on the composition of the glove (synthetic versus NRL) and its indicated uses (surgeon's glove versus patient examination glove). While we acknowledge that powdered synthetic patient examination gloves present less risk than powdered NRL surgeon's gloves, we concluded that the risks posed by either of these glove types is unreasonable and substantial in relation to the minimal benefits that powdered gloves offer, especially when considering the benefits and risks posed by readily available alternative devices (discussed in section II.C). The identified risks of powdered gloves are as follows:

1. Risks of Absorbable Powder for Lubricating a Surgeon's Glove

The powder used for lubricating a surgeon's glove, which is often used to lubricate patient examination gloves as well, presents risks not only to the user and patient, but also to other individuals that might be exposed to it. This powder, often referred to as Absorbable Dusting Powder or ADP, has been shown to cause acute severe airway inflammation, granulomas, and adhesions. These risks are present before the glove is lubricated with the powder. Then, during the lubrication process, the powder particles may absorb harmful contaminants (Ref. 15). As mentioned previously, the risks presented by glove powder can vary depending on the type of glove on which it is used. When used on NRL gloves, powder has the ability to adhere to latex allergenic proteins that, when aerosolized and inhaled, present significant risks to patients, including inflammatory responses, hypersensitivity reactions, and allergic reactions (see risks on powdered NRL gloves in the paragraphs that follow). Additionally, latex sensitive individuals can experience cutaneous reactions upon skin exposure to the latex allergenic proteins adherent to the powder (Refs. 15 and 16). These consequences of powder may persist even after patients or health care workers are no longer in contact with the powder. Risks such as allergic reactions, granulomas, and adhesions can be long-lasting, and may not be mitigated by removing powder after exposure (Refs 17 to 19).

2. Risks of Powdered Natural Rubber Latex Gloves

When absorbable dusting powder is used on NRL gloves, the combination presents specific risks that apply to both surgeon's and patient examination gloves. The powder used to lubricate these gloves may bind to natural rubber latex proteins. The powder carries the latex protein, resulting in a latex aerosol whenever health care workers put on or remove the gloves. Clinical and laboratory studies indicate that glove powder facilitates impaired respiratory function due to allergic and inflammatory responses to NRL in health care personnel and in animals exposed to glove powder because

aerosolized powder particles carrying NRL antigens into the health care environment and the respiratory tracts of exposed health care personnel and patients make NRL sensitization a much more efficient process than it would be in the absence of glove powder (Ref. 8, 20 to 23). As a result, health care workers that are sensitive to latex occasionally develop allergic reactions when they inhale too much powder. Sensitization to latex and subsequent allergic reactions also may result from exposure to aerosolized powder carrying the NRL proteins (Ref. 24). Allergic reactions include asthma, allergic rhinitis, conjunctivitis, and dyspnea. As discussed in the paragraphs that follow, the majority of studies suggest that use of low NRL protein powder-free gloves significantly reduces occupational asthma and the incidence of individuals developing allergies to NRL in the health care workplace (Refs. 21, 23, 25 to 35).

3. Risks of Powdered Synthetic Surgeon's Gloves

Although powdered synthetic surgeon's gloves do not present the risk of allergic reactions due to aerosolized powder that is carrying latex, the use of powdered synthetic gloves still presents the risk of exposing individuals to the powder via inhalation, which can lead to airway inflammation. Additionally, use of these gloves by health care providers can expose patients' tissues during surgery and invasive examinations to deposits of glove powder, which could then result in granuloma formation in any exposed site, as well as peritoneal and other tissues adhesions. Recent studies show that cornstarch glove powder causes peritoneal adhesion formation and granulomatous reactions in experimental animal models (Refs. 24, 36 to 39) as well as in exposed patient tissues with resulting patient injury (Refs. 40 and 41). In addition to risk of powder-induced adhesion formation, many in vitro and animal studies have shown the adverse effects of glove powder on wound healing, including increases in wound inflammation (Refs. 42 to 44). These studies indicate that powder may promote infection in wounds, which can lead to wound healing complications.

4. Risks of Powdered Synthetic Patient Examination Gloves

Although the powder on patient examination gloves is not exposed to internal organs during surgery, these gloves still present a substantial risk of illness or injury because they are nevertheless exposed to internal tissue when employed in procedures such as oral, vaginal, gynecological, and rectal examinations. Powder may be introduced to the female reproductive tract during gynecological exams (Refs. 45 to 47), which may lead to female reproductive complications (Refs. 18, 48 to 50). The migration of powder into the reproductive tract was demonstrated in an animal model and human clinical studies (Refs. 21, 40, 51). The wearers of these gloves can also facilitate the migration of powder from these gloves into the body when handling instruments such as endoscopes or when performing postsurgical wound care. Thus, the powder on synthetic patient exam gloves presents risks similar to those of the powder on synthetic surgeon's gloves, including granulomas and adhesions, and the resulting complications. Finally, as with synthetic surgeon's gloves, powdered patient examination gloves also can expose those in their proximity to the risk of powder inhalation, even if not carrying NRL.

C. State of the Art

FDA has considered the reasonableness of the risks of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's gloves relative to the state of the art, *i.e.,* the state of technical and scientific knowledge and modern practices of medicine, for medical protective gloves (see 44 FR 29214; May 18, 1979). Given that alternatives are readily available that do not carry the risks posed by powdered gloves, we have concluded that powdered gloves now lag behind the state of the art. As discussed further in sections II.D and II.E, this conclusion is illustrated both by market trends indicating that the health care industry is moving to non-powdered alternatives and by the actions of certain regulatory entities and professional organizations that have banned or restricted the use of glove powder.

Over the last two decades FDA has observed a progressive increase in the use of non-powdered gloves. Since 1998, medical glove manufacturers have developed a variety of non-powdered gloves, which can be made from various materials, including NRL, polyvinyl chloride, nitrile, and neoprene. Both non-powdered patient examination and non-powdered surgeon's gloves are currently marketed. These alternatives are readily available at similar costs to powdered gloves. As a result, both industry and glove users appear to be shifting away from the use of powdered gloves, which has led to an increase in the manufacturing and usage of alternative non-powdered gloves. Annual sales figures from 2000 through 2008 indicate a consistent increase in non-powdered surgeon's and patient examination glove sales as a percent of total glove sales, and recent projections of annual gloves sales indicate that at least 93 percent of medical providers have switched to non-powdered gloves (Ref. 52).

These trends can be at least partially attributed to scientific studies that have been conducted in this area that have helped raise public awareness of powder-induced latex hypersensitivity, peritoneal adhesions, granulomas, and other adverse events that can result from using powdered gloves. These trends can also be partially attributed to increased public awareness resulting from the availability of studies that have examined the effects of glove powder and the public health benefits that result from its removal from the market, along with industry initiatives to improve donning, doffing, and protection of non-powdered gloves, which have helped to move the state of the art forward to the use of alternative non-powdered gloves.

As described previously, some users of powdered gloves have noted ease of donning or doffing as a benefit over non-powdered gloves. However, 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. 53). Additional non-powdered alternatives to powdered gloves include synthetic gloves, which are traditionally non-powdered and offer similar levels of performance to powdered gloves and non-powdered NRL gloves (Refs. 9, 14, 54).

Studies that have examined the effects of removing powdered gloves from health care environments have shown that removing these devices consistently results in a reduction of the types of adverse events associated with glove powder. Korniewicz et al. examined the effect of conversion from powdered NRL surgical gloves to non-powdered NRL surgical gloves on operating room personnel (Ref. 32). This study found that conversion to non-powdered NRL gloves reduced adverse events related to exposure to NRL, including a significant decrease in skin and upper respiratory symptoms. During the course of the study, the authors also evaluated user satisfaction for non-powdered gloves and found that users rated their satisfaction, on average, the same or better than before conversion from powdered gloves to non-powdered

gloves in categories including quality, comfort, safety, performance, standardization, and needle stick injuries.

In another study on the effects of eliminating powdered NRL gloves from a hospital, Allmers et al. found that eliminating powdered NRL gloves reduced aerogenic NRL allergen loads and allowed latex-sensitized or latex-allergic health care workers to continue working (Ref. 25). Allmers et al. further assessed the effects of switching to non-powdered NRL gloves on the incidence of NRL allergy in personnel working in multiple health care facilities insured by the German Professional Association for Health Services and Welfare (Ref. 27). This study concluded that there was a significant correlation between an increase in the purchase of non-powdered NRL gloves and a decline in NRL-induced occupational asthma. In a subsequent study, Allmers et al. further showed that a reduction in the use of powdered NRL gloves correlated with a dramatic decline in reported NRL-induced occupational skin disease (Ref. 26). The authors of these studies concluded that removing powdered NRL gloves from health care environments successfully reduced the development of NRL-induced allergies. These observations have been confirmed by several other studies that are described further in section II.D (Refs. 21, 30, 32 to 35, 55).

FDA also expects that the removal of powdered gloves from health care environments will reduce the risks of using powdered synthetic gloves, such as granuloma formation in any exposed site, as well as peritoneal and other tissues adhesions. As discussed previously, recent literature has shown that cornstarch glove powder causes peritoneal adhesion formation and granulomatous reactions in experimental animal models (Refs. 24, 36 to 39) as well as in exposed patient tissues with resulting patient injury (Refs. 40 and 41). In addition to risk of powder-induced adhesion formation, many in vitro and animal studies have shown the adverse effects of glove powder on wound healing, including increases in wound inflammation (Refs. 42 to 44). Non-powdered gloves do not carry these risks, and their exclusive use should greatly reduce the risk of these adverse health effects in health care settings.

In comparison to the evidence considered in 1997, FDA has concluded that this proposed ban would likely have minimal economic and shortage impact on the health care industry, such that, if they have not already, health care entities that currently use powdered gloves should have little trouble transitioning to non-powdered alternatives. As described previously, there are many readily available alternatives to powdered gloves that provide similar or better protection and utility without the risks associated with powdered gloves, and available market projections and data have shown that these alternatives that represent the state of the art have already resulted in a shift away from powdered gloves. Further, more studies are now available on the positive health benefits associated with the restriction or elimination of the use of powdered gloves in health care environments where they were previously prevalent. Based on an examination of all these factors, FDA has determined that the state of the art, *i.e.,* the state of technical and scientific knowledge and modern practices of medicine, has moved beyond the use of powdered gloves in the health care industry.

D. Scientific Literature

In 1997, FDA issued the Medical Glove Powder Report (Ref. 5), discussing the potential adverse health effects of medical glove powder, along with alternatives and market information available at that time. Adverse health events documented in the scientific literature review section of the Medical Glove Powder Report included a discussion on aerosolized glove powder on NRL gloves carrying allergenic proteins that efficiently sensitized health care providers to NRL antigens. This exposure subsequently triggered respiratory allergic reactions including asthma and allergic rhinitis, conjunctivitis, and dyspnea. In addition, as discussed previously, the powdered gloves of health care providers expose patients to certain risks, including granuloma formation, as well as peritoneal and other tissue adhesions when exposed during surgery or an invasive procedure.

Since the publication of the Medical Glove Powder Report, there have been additional scientific studies published regarding the risks related to the use of medical glove powder. Many of these references were submitted to the Agency in support of the petitions received in 2008, 2009, and 2011. We also performed our own review of the scientific literature to ensure that all available evidence, including all available scientific evidence, was considered in its decision-making process. The most relevant articles gathered from these sources are briefly summarized in this document.

Clinical and laboratory studies published after 1998 still indicate that glove powder facilitates impaired respiratory function due to allergic and inflammatory responses to NRL in health care personnel and in animals exposed to glove powder because aerosolized powder particles carrying NRL antigens into the health care environment and the respiratory tracts of exposed health care personnel and patients make NRL sensitization a much more efficient process than it would be in the absence of glove powder (Refs. 8, 20 to 23). The newer studies also continue to show that cornstarch glove powder causes adhesion formation and granulomatous reactions in experimental animal models (Refs. 24, 36 to 39), as well as in exposed patient tissues with resulting patient injury (Refs. 40 and 41).

In vitro and animal studies continue to show the adverse effects of glove powder on experimental wound healing, including increases in wound inflammation (Refs. 42 to 44). Most importantly, since 1997, more data have become available on the positive health benefits associated with the restriction or elimination of the use of powdered gloves in health care environments where they were previously permitted. We reviewed studies from clinics and hospitals that have converted to either non-powdered NRL gloves or to powder-free gloves of all materials. These studies reported reductions in NRL allergy development and respiratory symptoms among health care workers (Refs. 20, 21, 23, 25 to 27, 29 to 34, 39). Although this has not been a universal finding, FDA recognizes the positive association between decreased usage of glove powder, especially on NRL gloves, and decreased adverse health events in the health care setting.

Epidemiological studies comparing the adverse health events and economic consequences in health care settings before and after conversion to powder-free gloves have limitations, such as the size of studies, the endpoint data collected, and the different populations studied. Some studies include the period before the amount of NRL protein in surgical and examination gloves was reduced. Others were performed abroad where U.S. regulations do not apply and the amounts of NRL protein and powder remaining on gloves are not stated. Despite these limitations, the preponderance of evidence suggests that use of low NRL protein powder-free gloves significantly reduces occupational asthma and the incidence of individuals developing allergies to NRL in the health care workplace (Refs. 20, 21, 23, 25 to 27, 29 to 34, 39). Importantly, these studies did not report

difficulty in replacing powdered gloves with non-powdered ones and did not note any decrease in glove performance in the replacement gloves (Refs. 32, 53).

Charous et al. (Ref. 20) 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. Also in 2002, Kujala et al. (Ref. 22) studied NRL gloves agitated in laboratory test chambers and found that the concentration of airborne NRL allergens correlated with high levels of airborne glove powder rather than with the NRL antigen concentrations in the medical glove material. In addition, Ahmed et al. (Ref. 8) reviewed the literature to 2004 on occupational NRL allergy and concluded that the use of low NRL protein powder-free gloves reduced symptoms and markers of sensitization in hospitals that had removed powdered NRL gloves from their workplaces; however, they noted that alternatives such as nitrile and vinyl gloves may not provide as good dexterity and biological impermeability as natural rubber latex gloves. The practicality of using non-powdered gloves was studied in 1998 by Cote et al. (Ref. 53) who performed a prospective randomized trial measuring the force required for volunteers to don various gloves in the laboratory without tearing the glove. They concluded that there were available powder-free gloves that can be donned easily with forces that are comparable to those required for powdered glove donning.

Individual hospitals, health care systems, regional authorities and countries have evaluated the extent of NRL allergies among their staff and the effects of removing glove powder from the gloves used in their facilities. In 1998, Handfield-Jones (Ref. 56) found that at least 0.9 percent of health care workers in an English district general hospital had confirmable NRL allergies. Anecdotal accounts suggested that problems had worsened as glove use increased. Allmers et al. (Ref. 25) in 1998 reported a prospective study in a single hospital in Germany to evaluate the effect of eliminating powdered NRL gloves from the workplace and also giving NRL-free gloves to sensitized workers. Six of seven sensitized health care workers showed a decrease in NRL-specific Immunoglobulin E antibody concentration during followup after the elimination of powdered NRL gloves in that hospital. Two other health care workers were able to stop using asthma medication and antiallergic drugs. The study authors concluded that eliminating powdered NRL gloves reduced aerogenic NRL allergen loads and allowed sensitized or allergic health care workers to continue working.

Not every physician or locality was equally concerned about the risk associated with the use of glove powder. In 1999, Sellar and Sparrow (Ref. 57) surveyed ophthalmologists in northern England and found that, despite relatively high awareness of risks associated with powdered glove use during ophthalmic surgery, such as sterile endophthalmitis or iritis in patients, up to 15 percent of surveyed United Kingdom ophthalmic surgeons were using powdered gloves in their surgical practices. However, in 2000, Petsonk (Ref. 58) found that the role of glove powder in binding and transferring NRL antigens was widely acknowledged in the scientific literature and noted that interventions, such as limiting the use of glove powder, seemed likely to result in a decline in the prevalence of NRL allergies. Additionally, in 2000, Jackson et al. (Ref. 31) reported that 70 hospitals in the United States and 3 in Europe had registered on an Internet Web site as institutions using only powder-free gloves; however, the article did not specify whether these hospitals had removed only NRL powdered gloves from their workplaces or whether synthetic latex powdered gloves were removed from use as well, and the Web site is no longer registered. The conclusion of Jackson et al. was that the leadership shown by the hospitals that registered as not using powdered gloves should serve as a catalyst for FDA to ban the use of cornstarch on examination and surgical gloves.

In 2001, Liss and Tarlo (Ref. 33) reviewed the number of allowed occupational asthma claims in health care workers reported to the Ontario Workplace Safety and Insurance Board over time as the replacement use of powder-free synthetic latex or low protein NRL gloves was encouraged, starting in 1996, throughout the province of Ontario. Reported health care-related occupational asthma claims ranged from 7 to 11 per year during 1991 to 1994 and fell to 1 to 2 claims per year in 1997 to 1999 as exposure to powdered NRL gloves decreased. Tarlo et al. (Ref. 55) also reported on the experience with occupational allergy to NRL in an Ontario teaching hospital network of two hospitals. In this hospital system, the number of workers identified with NRL allergy each year rose from 1 in 1988 to 6 in 1993 and to 25 in 1994 after staff education and surveillance for the manifestations of NRL allergy. Powder-free, low protein NRL gloves replaced non-sterile gloves in 1995 in this hospital system, after which new workers with reported NRL allergy dropped to eight in 1995, to three in 1997 and to one in 1999. NRL allergy-related time lost from work and workers' compensation claims fell significantly after powder-free, low protein NRL gloves replaced powdered non-sterile gloves in this Ontario hospital system. In 2002, Saary et al. (Ref. 23) resurveyed the upper-year students and faculty of a dental school in Ontario for NRL allergy using the same methods as those used in the study performed by Tarlo et al. (Ref. 55). In 1995, the school was using powdered NRL gloves in patient care. Following the 1995 survey, the school changed to powder-free, low protein NRL gloves. In 2000, the incidence of positive prick tests to NRL fell from 10 percent (in 1995) to 3 percent and there were significant reductions in the incidence of urticaria and immediate pruritus after glove contact reported by the dental students.

Allmers et al. (Ref. 27) reported in 2002 occupational allergy to NRL data from the German Professional Association for Health Services and Welfare, which covered approximately half of all German hospitals and all dental offices. In 1998, Germany banned the use of powdered NRL gloves in health care facilities. From 1996 through 2001, the incidence of suspected occupational NRL allergy declined steadily as the use of powder-free NRL examination gloves and powder-free NRL sterile gloves overtook the use of powdered gloves in 1998 and 2000, respectively, in German acute care hospitals. The authors concluded that primary prevention of occupational NRL allergies could be achieved through practical interventions such as decreasing the use of powdered NRL gloves. Allmers et al. (Ref. 26) reassessed the effects of the 1998 German ban on powdered NRL gloves in 2004 and found that between 1996 and 2002, the incidence of suspected cases of NRL-induced occupational allergies reported to the German statutory accident insurance carrier decreased by almost 80 percent.

Charous et al. (Ref. 28) reviewed the scientific literature available in 2002 and subsequently recommended using only non-powdered sterile NRL gloves or low-protein NRL powdered sterile gloves as evaluation of the effect on occupational NRL allergic reactions continued, in order to reduce the burden of NRL allergy and its effects on health care personnel. Cuming (Ref. 29) also noted that the link between glove powder and the occurrence of NRL allergies and postoperative

complications in surgical patients was well supported scientifically and described how his four hospital system (not identified) with multiple ambulatory care centers and associated medical practices successfully eliminated powdered glove use after appropriate alternate glove product evaluation.

Edelstam and colleagues (Ref. 21) described the implementation of a powder-free environment in a Stockholm hospital. These authors administered symptom questionnaires to hospital staff designed to detect symptoms highly suggestive of occupational NRL allergy. They found that 8 months after a powder-free policy was fully implemented in the hospital there was a significant reduction in reported hand itching, eczema, and upper respiratory tract disorders in health care workers. The authors also noted that reduced costs associated with lower work absence rates may offset higher costs associated with the use of powder-free medical gloves.

In 2005, Korniewicz et al. (Ref. 32) examined whether switching to low NRL protein powder-free surgical gloves in the operating room suite of a single U.S. university hospital was worth the cost. Surveys prior to and 7 to 12 months after the conversion to powder-free surgical gloves found that 27 percent fewer health care workers reported skin symptoms and 12 percent fewer health care works reported upper respiratory symptoms related to NRL exposure. These authors concluded that the use of powder-free low protein NRL gloves reduced symptoms and resulted in workers compensation cost savings. In addition, because fewer different types of gloves were purchased after the conversion to non-powdered surgical gloves, a glove cost savings of $10,000 per year was estimated for the hospital. In a 2006 report, Filon and Radman (Ref. 30) described the results of following 1,040 health care workers in Trieste for 3 years before and after the introduction of powder-free gloves with low NRL levels. After the introduction of powder-free gloves, no new cases of NRL allergy, as diagnosed by skin test hypersensitivity to NRL were identified in the followup survey. The authors concluded that avoiding unnecessary NRL glove use and using non-powdered NRL gloves (and non-NRL gloves for sensitized health care workers) could stop the progression of symptoms of NRL allergy and avoid new cases of health care provider sensitization to NRL.

In 2008, Malerich et al. (Ref. 34) studied the effect of transitioning from powdered to powder-free NRL gloves on workers' compensation claims in a U.S. multihospital system, the Geisinger Health System, between 1997 and 2005. They estimated that 52 percent of the system work force at that time was occupationally exposed to NRL gloves. In 2001, the system transitioned to powder-free NRL gloves. The incidence of NRL-related workers' compensation claims decreased progressively after 2001, from 62 claims over the 5 year period before the change to only 18 claims in the next 4 years. The average annual savings in NRL-related compensation claims was estimated to be over $30,000. Although the cost of the powder-free NRL gloves resulted in a 36 percent increase in the cost of gloves, this was partially offset by the elimination of the costs of washing powder off the surgical gloves, estimated at about $57,000.

Vandenplas et al. (Ref. 35) reported in 2009 on changes in the incidence of NRL-related occupational asthma (OA) claims from health care providers submitted to the Workers' Compensation Board of Belgium from 1992 through 2004. Definite and probable NRL-related OA incidence per 100,000 full-time equivalents for health care workers was 10.9 per 100,000 in 1991, 19.7 per 100,000 in 1998, and 3.8 per 1,000,000 in 2003. The overall usage index of NRL-powdered glove use was 80.9 percent in 1989 and fell to 17.9 percent by 2004. The non-sterile NRL-powdered glove use index fell from 80.5 percent to 14.4 percent. However, the sterile procedure, NRL-powdered glove use index changed only from 84.6 percent to 48.9 percent over this 15-year period.

Although the adverse event risks of glove powder on a variety of tissues were well-documented before 1997, investigations to understand the pathogenesis of tissue damage caused by glove powder have continued. In 1999, Chegini and Rong (Ref. 36) studied the effect of glove powder, NRL proteins, and lipopolysaccharide added directly to the peritoneal cavity of mice and found that glove powder worsened the inflammatory response to tissue injury caused by NRL proteins and lipopolysaccharide alone. The study suggested that this interaction could contribute to inflammatory or immune reactions and the development of adhesions after abdominal surgery. Sjösten et al. (Ref. 38) published a study in 2000 showing that the intravaginal deposition of free glove powder in rabbit vaginas prior to laparotomy led to dense pelvic adhesions and even attachment of the Fallopian tube to the peritoneal wall after laparotomy with standardized trauma on the left Fallopian tube and the ipsilateral peritoneum. The control group was not exposed to glove powder and experienced only loose adhesions after laparotomy with standardized trauma. The authors recommended against the use of powdered gloves during gynecologic surgery.

In 2001, van den Tol et al. (Ref. 39) found that starch, either washed from gloves or pure base starch, when added to the peritoneal cavity of rats during laparotomy plus surgical peritoneal trauma, caused increased peritoneal adhesion formation. When tumor cells were added to the peritoneal cavity at the end of the experimental surgery, increased adhesion and growth of the tumor cells occurred in rats who also received powder contamination of the peritoneal cavity. These authors recommended that powdered gloves no longer be used during intra-abdominal surgery on the basis of these results. In 2003, Barbara et al. (Ref. 24) found that after guinea pigs were sensitized to NRL antigens, with or without added cornstarch powder given by intraperitoneal injection, the guinea pigs who received NRL antigens mixed with cornstarch had increased antibody production and antigen-induced constriction of the bronchial tubes when challenged with an aerosol of NRL antigens compared to animals who received intraperitoneal NRL antigens alone. They concluded that cornstarch powder used as a donning agent on NRL gloves can increase sensitization to NRL compared to exposure to NRL antigens alone.

In 2002, Smither et al. (Ref. 41) presented a case report of a 58-day-old male infant with bilateral scrotal masses due to a foreign body reaction to glove powder following a pyloromyotomy performed shortly after birth. In 2004, Sjösten et al. (Ref. 40) extended their prior work on the adverse effects of glove powder in animals to a clinical observational study. They found that in patients who underwent vaginal examination 1 or 4 days prior to a scheduled hysterectomy with either powdered or non-powdered gloves, examination of the removed tissues postoperatively detected more starch particles in the cervix and uterus of patients examined with powdered gloves. There were no differences between the patient groups in the numbers of starch particles seen in the distant sites of the Fallopian tubes or the peritoneal fluid. In 2 patients examined with powdered gloves, no starch particles were found, and 3 patients examined with only powder-free gloves had a few starch particles in their tissues.

Odum et al. (Ref. 43) studied a guinea pig model of paravertebral abscess formation. They reported that when slurries of either calcium carbonate ($CaCO_3$) or cornstarch were added to guinea pig wounds along with *Staphylococcus aureus,* the wounds with added $CaCO_3$ had higher bacterial counts 4 days later than did the wounds with added cornstarch, and both had higher bacterial counts than the control wounds with only *S. aureus* inoculated. This study was considered by the authors to support an increased risk of wound infection after wound exposure to powdered gloves. In addition, Dave et al. (Ref. 42) reviewed the literature on glove powder relating to dental powdered glove use and noted that cornstarch promoted wound infection in reported animal model studies and that cost-effective powder-free gloves were available. The authors recommended the use of non-powdered gloves in place of powdered gloves. Dwivedi et al. (Ref. 37) studied both NRL and synthetic latex gloves, both powdered and unpowdered in a rat laparotomy model. They found that both non-powdered natural rubber latex and powdered surgical gloves resulted in peritoneal adhesions. However, powdered NRL gloves further promoted increased tissue adhesions, which correlated with elevated serum cytokine levels. They suggested that the use of NRL free, powder-free gloves would be most effective in decreasing peritoneal adhesion formation. In 2010, Suding et al. (Ref. 44) performed another study of the effect of cornstarch on experimental model abscess formation. They found that the injection of starch into wound sites increased the likelihood of methicillin-resistant *S. aureus* injection abscess formation in a rat model.

E. Actions of Other Regulatory Entities and Professional Organizations

Over the past several years, some domestic health care organizations, health care systems, and other nations have banned or restricted the use of glove powder because of its deleterious effects on the body. Organizations such as the National Institute for Occupational Safety and Health (NIOSH), the American Academy of Allergy, Asthma, and Immunology (ACAAI), the American College of Surgeons (ACS), and the American Nurses Association have all issued statements discouraging the use of powdered NRL gloves (Refs. 59 to 61). In June 1997, the NIOSH of the CDC issued an Alert titled ''Preventing Allergic Reactions to Natural Rubber Latex in the Workplace'' (Ref. 59) in which it recommended that if NRL gloves are used in the workplace, they should not be powdered. The ACS issued a statement from their Committee on Perioperative Care in 1997 that recommended that surgeons should insist on using only non-powdered (''powder-free'') surgeons gloves (Ref. 62). The ACAAI issued a recommendation (Ref. 60) on the use of NRL gloves in 1997 and stated that only non-powdered (''powder-free'') NRL gloves should be purchased and used in order to reduce NRL aeroallergen levels and exposure to them.

Moreover, health care systems including the Johns Hopkins Hospital, the Cleveland Clinic's network of nine hospitals, and the University of Virginia Healthcare System have all restricted or banned the use of powdered NRL gloves in their facilities (Refs. 63–64). Finally, the international health care systems of Germany and the United Kingdom have also independently taken steps against the use of powdered NRL gloves due to the dangers of the devices and the hazards they pose in the health care setting (Refs. 65–66).

The Occupational Safety and Health Administration (OSHA) of the Department of Labor (DOL) issued a Technical Information Bulletin (TIB 99–04–12) in 1999 and updated it in 2008 (SHIB 01–28–2008) (Ref. 67) describing the risk of sensitization to natural rubber latex products used in the workplace. In both of its documents, OSHA recommended that, if NRL gloves must be used, they should be non-powdered (''powder-free'').

In the 1998 CDC Guideline for Infection Control in Hospital Personnel-1998 (Ref. 68), CDC addressed the issues of NRL sensitization in the health care workplace and recommended that the use of non-powdered natural rubber latex gloves would be more efficient than other interventions such as trying to wash powder off gloves in reducing NRL allergy in the workplace when NRL gloves were retained instead of replaced.

In January 2000, the New Jersey Department of Health and Senior Services (DHSS) issued ''Guidelines on the Management of Natural Rubber Latex Allergy; Selecting the Right Glove for the Right Task'' (Ref. 69) for the health care facility environment. The New Jersey DHSS recommended that reduced powder or, preferably, non-powdered NRL gloves be used when NRL gloves are selected.

Allmers and colleagues (Ref. 25) reported that a revised version of the technical regulations for dangerous substances (TRGS 540) was published in Germany in December 1997 that stated that the use of powdered natural rubber latex gloves was not permissible in the workplace; only ''powder-free'' NRL gloves could be used.

In the United Kingdom in 2008, the National Health Service (NHS) Plus Occupational Health Clinical Effectiveness Unit, in association with the Royal College of Surgeons, issued evidence-based guidelines (Ref. 70) on ''the occupational aspects of latex allergy management.'' These guidelines include the recommendation that when NHS employers determine that a NRL glove is the most suitable choice for use against a specific hazard, the NRL glove selected should be a low NRL protein glove without glove powder.

In 2011, the Association of Professionals in Infection Control and Epidemiology (APIC) responded to the FDA's request for comments on information related to risks and benefits of powdered gloves (Docket No. FDA–2011–N–0027). APIC stated (Ref. 71) that it supported the use of powder-free surgeon's gloves in health care. It stated also that it agreed with the position of the ACS and that of the Association of Perioperative Registered Nurses (AORN) that powdered gloves increase the risk of sensitization to NRL antigens. APIC also noted that the evidence for the role of glove powder in surgical site infection risk is limited.

F. Analysis of Medical Device Adverse Events Reported to FDA for Medical Gloves

On its own initiative, FDA evaluated adverse event reports for medical gloves that use powder as additional information to help determine whether the standard for initiating a ban was met and, if so, whether a ban was the appropriate regulatory action to address the unreasonable and substantial risk of illness or injury presented by powdered gloves.

We performed a search of our Manufacturer and User Facility Device Experience (MAUDE) database to isolate reports through September 30, 2015, to evaluate the number of adverse events reported for all types of medical gloves. A total of 3,780 reports were identified, including some that identify inflammation and granulomas. The reports retrieved in this query date back to 1992. Charting the reports entered by year indicates a bell curve in which the majority of reports were entered in 1999 with 783 reports. Since 1999, the number of adverse events reported for these devices has consistently decreased, and since 2003, the number of adverse events reported for these devices has tapered off to consistently remain below 100 per year. FDA believes that this reduction can be

attributed to the risks of powdered gloves becoming better known, which has led to suitable powder-free alternatives being developed and becoming more widely available on the market.

As discussed in section VIII ''Economic Analysis of Impacts,'' market analysis clearly indicates that use of powdered gloves is declining, but some individuals and organizations continue to use them despite the risks of illness or injury they present. As such, health care workers, patients, and other individuals who come in contact with glove powder are being exposed to risks unnecessarily, which is one of the reasons that FDA decided to initiate this ban.

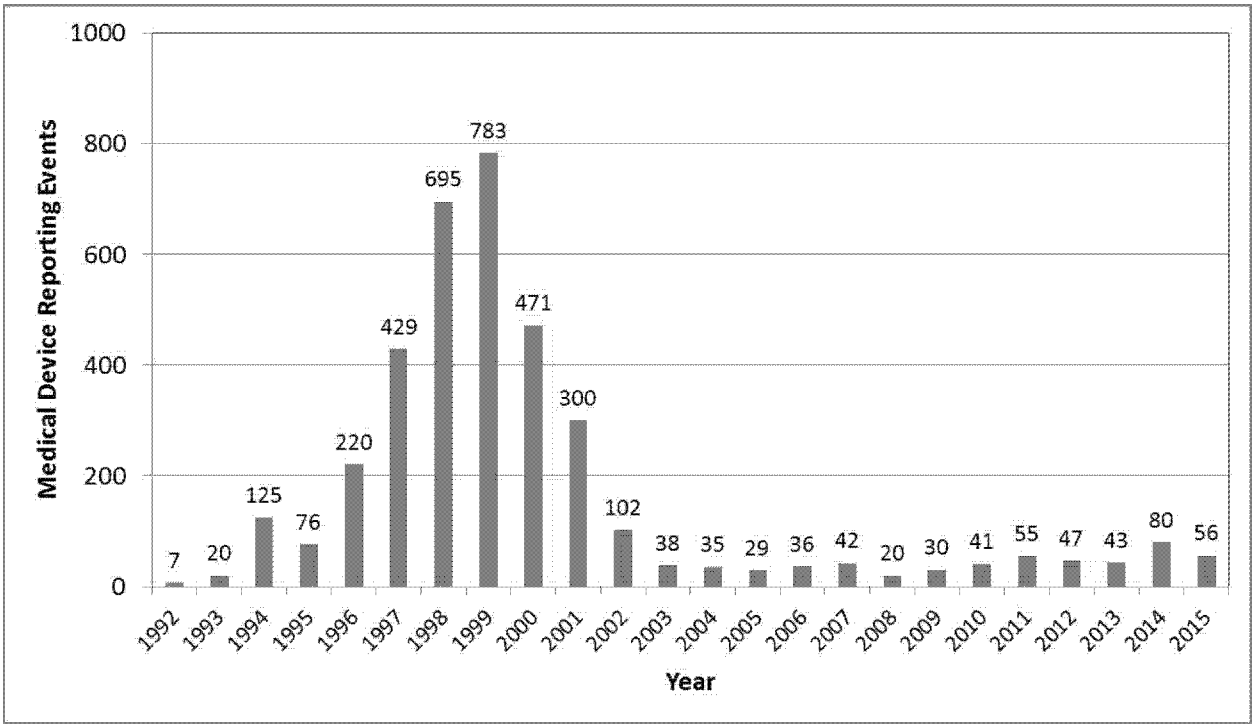

Figure 1.--Number of Reported Adverse Events, 1992-2015

III. The Reasons FDA Initiated the Proceeding; Determination That Powdered Gloves Present an Unreasonable and Substantial Risk of Illness

As described in section 1.D, 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'' In this section, we describe the reasons we initiated the proceeding to ban powdered gloves, including the determination that powdered gloves present an unreasonable and substantial risk of illness or injury. In order to make this determination, we analyzed both the benefits and the risks that these devices pose to those that may come into contact with them, comparing those benefits and risks to the benefits and risks posed by similar alternative devices.

As explained in section II, the level and types of risk presented by powdered gloves varies depending on the composition and intended use of the glove. While some glove types present less risk than others, we have concluded that the public's exposure to such risk is substantial in relation to the nominal public health benefit derived from the continued marketing of these devices. Further, it is FDA's position that exposure to these risks is unreasonable in the current market where suitable alternatives are readily available that carry none of the risks presented by powdered gloves.

The risk of acute severe airway inflammation due to ADP inhalation is a risk presented by all powdered glove types and absorbable powder alone and is considered important, material, and significant in relation to the minimal potential benefits of greater ease of donning and doffing and decreased tackiness. In considering these risks relative to the state of the art and alternative non-powdered gloves that do not present risks of acute severe airway inflammation, FDA has determined that these risks are substantial and unreasonable.

The risks of inflammatory responses, hypersensitivity reactions, and allergic reactions, including asthma, allergic rhinitis, conjunctivitis, and dyspnea, are risks presented by all powdered latex glove types. FDA has determined that these risks are important, material, and significant risks in relation to the minimal potential benefits of greater ease of donning and doffing and decreased tackiness. In relation to the state of the art of alternative non-powdered gloves that do not present risks of inflammatory responses, hypersensitivity reactions, and allergic reactions, we conclude that these risks are substantial and unreasonable.

The risk of granuloma and adhesion formation is presented to patients and health care workers via exposure to internal tissue through the use of powdered latex or synthetic surgeon's and patient examination gloves. FDA has determined that this risk is important, material, and significant in relation to the minimal potential benefits of greater ease of donning and doffing and decreased tackiness. In relation to the state of the art of

alternative non-powdered gloves that do not present risk of granuloma and adhesion formation, we have concluded that this risk is substantial and unreasonable.

A critical aspect of these devices that FDA considered in coming to the decision to propose this ban is their ability to affect persons other than the individual who decides to wear or use them. 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 of those gloves. Glove powder's expansive danger zone includes persons, including other health care workers, completely unaware or unassociated with its employment. In addition, users wear gloves as a conventional prophylactic measure to prevent harm, but may be exposed to the myriad harms posed by powdered gloves. Although we have noticed a progressive reduction in the market share of powdered gloves, some individuals and institutions continue to use them. This, in turn, has led to continued exposure to the risks presented by powdered gloves.

In aggregate, the risks posed by these devices 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. 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. The benefits of these devices appear to only include ease of donning and doffing and increased tackiness. We have concluded that these benefits are nominal, and that the risks that are posed by the continued marketing of powdered gloves outweigh those benefits in all instances, especially in light of the current state of the art, and the fact that readily available alternatives exist in today's market that carry none of these risks. As such, FDA has determined that the standard to ban powdered gloves has been met, and that it is appropriate to issue this proposal to ban.

IV. FDA's Determination That Labeling, or a Change in Labeling, Cannot Correct or Eliminate the Risk

FDA 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 to individuals, and that no change in labeling could correct the risk of illness or injury presented by the continued use of these devices. FDA has determined that a ban is the appropriate regulatory approach to addressing risks posed by glove powder. No labeling or warnings can mitigate the risks posed by these devices.

As discussed previously, powdered gloves have additional or increased risks to health compared to non-powdered gloves related to the spread of powder and powder-transported contaminants such as latex allergens through aerosols and inhalation or direct or indirect contact with wounds, oral, vaginal, rectal tissue, etc. Although labeling can raise awareness of these risks, we do not conclude that labeling can 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. Glove powder's expansive danger zone includes 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 cannot be written that would ensure the safe and effective use of these devices for all persons that might come in contact with them.

In the now withdrawn draft guidance entitled ''Draft Guidance for Industry and FDA Staff: Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder,'' FDA proposed a general voluntary warning for powdered glove devices in order to alert users to the potential adverse health effects of medical glove powder while FDA assessed the benefits and risks of glove powder (Ref. 7) (80 FR 26059). In order to facilitate this assessment, concurrent with the issue of this draft guidance document, we issued a notice in the **Federal Register** requesting public input on the benefits and risks of powdered gloves (76 FR 6684, February 7, 2011; FDA–2011–N–0027). Many of the comments we received, in addition to a citizen petition filed in 2011 (FDA–2011–P–0331–0001), indicated that labeling would not sufficiently address the risks posed by glove powder because a warning label would not be visible to everyone affected by risks of glove powder.

Although the use of powdered gloves has declined in recent years, the use of these devices has not been eliminated, and patients and health care workers continue to be exposed to the risks of glove powder. Due to the ability of powder to affect people who would not have an opportunity to read warning labels, such a label would be ineffective at informing the affected persons of potential risks. In addition, potential warning labels would raise awareness of the risks, but would not eliminate the risks posed by glove powder. Therefore, despite declining use of powdered gloves and previous warning label suggestions, FDA has determined no label or warning can mitigate the risks posed by these devices.

Due to the nature of the risks presented by glove powder that are posed simply by virtue of the powder being used, we do not conclude that additional or new labeling can adequately correct or eliminate the risks. As such, in light of all available data and information, FDA has determined that it should address the risks posed by glove powder by banning its use.

V. FDA's Determination That the Ban Applies to Devices Already in Commercial Distribution and Sold to Ultimate Users, and the Reasons for This Determination

FDA has determined that this ban, if finalized, 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 thus adulterated under section 501(g) of the FD&C Act and would be subject to enforcement action.

FDA made this determination because the risks of illness or injury to individuals who are currently exposed to these devices is equally unreasonable and substantial as it would be for future individuals that might be exposed to powdered gloves. Indeed, because suitable alternatives already exist in the current marketplace, and because the market trends have shown that powder glove use is steadily decreasing, it is likely that the remaining users of powder gloves will be able to quickly transition to alternatives that are equally effective and carry none of the risks associated with powdered gloves. Further, because of the steady decrease

in powdered glove use, it is likely that the greatest number of people that might benefit from the ban include those who would be exposed to powdered gloves already in distribution. It is our conclusion that this group is being unnecessarily exposed to risks that can be eliminated through the use of alternative gloves that are readily available. For these reasons, FDA has determined that the ban should apply to powdered gloves and glove powder already in commercial distribution.

VI. Legal Authority

This proposed rule, if finalized, would amend §§ 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).

VII. Environmental Impact

FDA has carefully considered the potential environmental effects of this proposed rule and of possible alternative actions. In doing so, we 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. The proposed 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 at user facilities nationwide, followed by a rapid decrease in the rate of disposal of these devices, as supplies are depleted. The proposed 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 proposed action is expected to have no significant impact on landfill and solid waste facilities and the environment in affected communities.

The Agency has concluded that the proposed rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday (Ref. 72). FDA invites comments and submission of data concerning the EA and FONSI.

VIII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed 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 proposed rule. We believe that this proposed 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 propose to certify that the final rule would 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 proposing ''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 $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary

The proposed rule, if finalized, would prohibit 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. In the past, powdering gloves was a popular method to make the gloves easier to put on and remove. However, recent studies indicate that these powders pose an unnecessary risk to medical workers (Ref. 73 and 74). Their results note that these powders carry the latex material on latex gloves. As a result, medical workers who are sensitive to latex are occasionally exposed to enough latex to develop an allergy.

Adopting the proposed 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 because improvements to non-powdered gloves have made these products as affordable and easy to put on as powdered gloves. The ban is expected to reduce the adverse events associated with using powdered gloves. Total annual benefits are estimated to range between $26.6 million and $29.3 million.

The Economic Analysis of Impacts of the proposed rule performed in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act is available at *http://www.regulations.gov* under the docket number(s) (FDA–2015–N–5017) for this proposed rule and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 75). We invite comments on this analysis.

IX. Proposed Effective Date

FDA is proposing that any final rule based on this proposed rule become effective 30 days after the date of its publication in the **Federal Register**. FDA proposes that manufacturers must not market any new units of affected devices after the effective date of any final rule based on this proposal. FDA requests comment on the proposed effective date for this proposed rule. Once this rule is finalized, all powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's gloves must be removed from the market by the effective date provided in the final rule or the device will be deemed adulterated. Section 501(g) of the FD&C

Act deems a device to be adulterated if it is a banned device.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain State requirements ''different from or in addition to'' certain Federal requirements applicable to devices (21 U.S.C. 360k; See *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008)). This proposed rule, if finalized, would create a requirement under 21 U.S.C. 360k that bans Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove.

XII. 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 *http://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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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, it is proposed that 21 CFR parts 878, 880, and 895 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR 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 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 made of natural rubber latex or synthetic latex, intended to be worn by 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 21 CFR 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 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 made of either natural rubber latex or synthetic latex, 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 21 CFR part 895 continues to read as follows:

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

■ 7. Add § 895.102 to subpart B to read as follows:

§ 895.102 Powdered surgeon's glove.

A powdered surgeon's glove is a device made of natural rubber latex or synthetic latex, intended to be worn by operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

■ 8. Add § 895.103 to subpart B to read as follows:

§ 895.103 Powdered patient examination glove.

A powdered patient examination glove is a disposable device made of natural rubber latex or synthetic latex, 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.

■ 9. Add § 895.104 to subpart B 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: March 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–417C]

Schedules of Controlled Substances: Placement of UR–144, XLR11, and AKB48 Into Schedule I; Correction

AGENCY: Drug Enforcement Administration, Department of Justice.