Draft Guidance for Industry and FDA Staff

Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder

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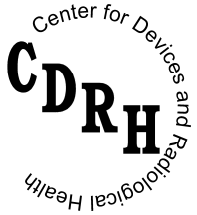

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Preface

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1. Introduction

This draft guidance recommends use of a warning statement on labels for powdered medical gloves, specifically surgeon's gloves (21 CFR 878.4460) and patient examination gloves (21 CFR 880.6250) (medical gloves that use powder).[1] FDA is concerned about the potential adverse health effects from powdered medical gloves and is recommending that the labeling for medical gloves that use powder provide a warning related to those potential health effects.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Scope

This draft guidance applies to medical gloves that use powder, specifically surgeon's gloves (21 CFR 878.4460) and patient examination gloves (21 CFR 880.6250) that use powder,[2] with the following product codes:

Classification (21 CFR)	**Product Code**	**Product Code Description**
878.4460	KGO	Powdered latex surgeon's gloves
878.4460	OPG	Powdered synthetic/non-latex surgeon's gloves
880.6250	OPB	Powdered polychloroprene patient examination glove
880.6250	OPD	Powdered nitrile patient examination glove
880.6250	OPE	Powdered latex patient examination glove
880.6250	OPF	Powdered vinyl patient examination glove

FDA is issuing this draft guidance with labeling recommendations because of concerns that users and patients may not be aware of the potential adverse health effects associated with these devices. This draft guidance provides a recommended labeling warning intended to complement FDA's 2008, "Guidance for Industry and FDA Staff - Medical Glove Guidance Manual" (**http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073111.htm#4d**) and FDA's 2004, "Guidance for Industry and FDA Staff: Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" **(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072528.htm).** If this draft guidance is finalized, FDA will update these two glove-related guidances to reflect the labeling recommendations.

3. Background

In 1997, FDA issued the "Medical Glove Powder Report" discussing the potential adverse health effects of medical glove powder, along with alternatives and current market information available at that time (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm113316.htm). Adverse health events reviewed by the Medical Glove Powder Report included (a) aerosolized powder on natural rubber latex (NRL) gloves carrying allergenic

proteins as a cause of respiratory allergic reactions, (b) rhinitis, conjunctivitis and dyspnea, (c) respiratory problems, (d) granuloma formation, and (e) peritoneal adhesions. Since that time, there have been more studies regarding the risks related to medical glove powder. These clinical and laboratory studies published after 1997 indicate cornstarch glove powder affects wound healing, inflammation, adhesion formation, granulomatous peritonitis, respiratory function, as well as allergic responses.[3-23] FDA has reviewed studies from clinics and hospitals that have converted completely to powder-free gloves, indicating reduction in allergy development and respiratory issues among health care workers.[18,24-36] However, this has not been a universal finding.[37]

Epidemiology studies comparing the economic and adverse health events in healthcare settings before and after conversion to powder-free gloves have limitations. However, the preponderance of evidence suggests that use of low protein powder-free gloves significantly reduces occupational asthma and incidence of individuals developing allergies to NRL. [18, 26-36]

FDA is issuing this draft guidance with a recommended warning statement for powdered medical gloves, informing users of the potential adverse health effects from these devices, including foreign body reaction, formation of granulomas, and peritoneal adhesion, especially with multiple surgeries. The warning should also include information on increases in respiratory ailments, and the development of irritant dermatitis or Type IV allergy when glove powder is used on NRL gloves. In addition, the warning should state that powder used on NRL medical gloves can serve as a carrier for airborne allergenic natural rubber latex proteins. Manufacturers who choose to use a warning other than the one provided below should ensure that the labeling addresses the risks inherent to powdered gloves.

4. Recommended Warning Statement

Because of the concerns related to the potential adverse health effects from use of medical gloves that use powder and to ensure compliance with section 502 of the Federal Food, Drug, and Cosmetic Act and 21 CFR 801.5, FDA recommends that labeling for medical gloves that use powder include the following warning statement:

Warning: Powdered gloves may lead to foreign body reactions and the formation of granulomas in patients. In addition, the powder used on gloves may contribute to the development of irritant dermatitis and Type IV allergy, and on latex gloves may serve as a carrier for airborne natural latex leading to sensitization of glove users.

FDA recommends that manufacturers of powdered gloves include this change to their product labeling no later than six months after issuance of final guidance based on this draft, and sooner if possible.

5. References

1. For more information on "medical gloves," see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073111.htm.
2. Absorbable powder for lubricating a surgeon's glove is a class III device, subject to premarket approval application (PMA), see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072528.htm.
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