Draft Guidance for Industry and FDA Staff

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

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

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Preface

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Table of Contents

1. INTRODUCTION ................................................................. 4
2. SCOPE ............................................................................... 5
3. BACKGROUND ....................................................................... 5
4. RECOMMENDED WARNING STATEMENT ............................. 7
5. REFERENCES ........................................................................ 7
Draft Guidance for Industry, Clinical Laboratories and FDA Staff

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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This draft guidance recommends use of a warning statement on labels for powdered medical gloves, specifically surgeon’s gloves (21 CFR 878.4460) and patient examination gloves (21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). 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FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities.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This draft guidance applies to medical gloves that use powder, specifically surgeon’s gloves (21 CFR 878.4460) and patient examination gloves (21 CFR 880.6250) that use powder, with the following product codes:

<table>
<thead>
<tr>
<th>Classification (21 CFR)</th>
<th>Product Code</th>
<th>Product Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>878.4460</td>
<td>KGO</td>
<td>Powdered latex surgeon’s gloves</td>
</tr>
<tr>
<td>878.4460</td>
<td>OPG</td>
<td>Powdered synthetic/non-latex surgeon’s gloves</td>
</tr>
<tr>
<td>880.6250</td>
<td>OPB</td>
<td>Powdered polychloroprene patient examination glove</td>
</tr>
<tr>
<td>880.6250</td>
<td>OPD</td>
<td>Powdered nitrile patient examination glove</td>
</tr>
<tr>
<td>880.6250</td>
<td>OPE</td>
<td>Powdered latex patient examination glove</td>
</tr>
<tr>
<td>880.6250</td>
<td>OPF</td>
<td>Powdered vinyl patient examination glove</td>
</tr>
</tbody>
</table>

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. 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. However, this has not been a universal finding.

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. 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
Contains Nonbinding Recommendations
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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.
15. Nafeh AI, Nosseir M Assessment of peritoneal adhesions due to starch granules of surgical glove powder an experimental study J Egypt Soc Parasitol 37(3) 835-842 2007
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21. Sjosten ACE, Ellis H, Edelstam GAB Post-operative consequences of glove powder used pre-operatively in the vagina in the rabbit model  Human Reproduct. 15(7), 1573-1577 2000
27. Hermesch CB, Spackman GK, Dodge WW, Salazar A Effect of Powder-free Latex Examination Glove Use on Airborne Powder Levels in a Dental School Clinic  J Dental Ed 63(11) 814-820 1999
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38. Garabrant DH, Schweitzer S Epidemiology of Latex Sensitization and Allergies in Health Care Workers J Allergy Clin Immunol 110, S82-95  2002