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Information Related to Risks and Benefits of Powdered Gloves; Request for Comments; Draft Guidance for Industry and Food and Drug Administration Staff; Recommended Warning for Surgeon's Gloves and Patient Examination Gloves That Use Powder; Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0027]

Information Related to Risks and Benefits of Powdered Gloves; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket to receive comments related to surgeon's gloves and patient examination gloves (medical gloves) that contain or use donning or dusting powder. FDA is interested in the potential health effects from the use of powder on medical gloves and is soliciting comments regarding risks and benefits of powdered gloves. FDA is interested in any potential benefits of powdered gloves so that the Agency can consider how best to address the risks in light of any benefits. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability for a draft guidance document entitled "Recommended Warning for Surgeon's Gloves and Patient Examination Gloves That Use Powder." The draft guidance document provides a recommended warning statement for powdered glove labeling that will inform health care providers and consumers of the risks associated with glove powder.

DATES: The Agency encourages interested parties to submit information and comments by April 25, 2011.

ADDRESSES: Submit electronic comments or information to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Paul Gadiock, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4432, Silver Spring, MD 20993, 301-796-5736, e-mail: paul.gadiock@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has received two citizen petitions (FDA-2008-P-0531-001 and FDA-2009-P-0117-001) requesting that FDA ban powder on surgeon's gloves

and patient examination gloves under the authority granted to FDA by section 516 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360f). In their submissions to FDA, the petitioners highlight the adverse health effects that can result from powdered glove use, including allergic reactions, irritation, and foreign body reactions resulting in inflammation, granulomas, and adhesions of peritoneal tissue after surgery, as well as glove powder's ability to serve as a carrier of endotoxin.

FDA has considered this information and believes the petitions have raised legitimate concerns about the use of powdered gloves. However, FDA's regulatory approach to powdered gloves must consider the risks of these gloves in light of any benefits. For example, if powdered gloves offer unique benefits in performing certain procedures, FDA should consider such benefits in determining how the risks of powdered gloves should be addressed. To assist the FDA in developing its regulatory approach, the Agency is seeking public input regarding the risks and benefits of powdered gloves to determine whether such gloves present an unreasonable and substantial risk of illness or injury. FDA is interested in comments on both the risks and the benefits of powdered gloves; however, because the risks associated with powdered glove use have been extensively discussed in the citizen petitions, FDA is particularly interested in whether there are any potential benefits that powdered gloves may offer. Comments related to the benefits of powdered glove use should also discuss whether those benefits are available when using nonpowdered gloves. FDA plans to use this information when considering how to address the risks in light of any known benefits.

Although FDA is still examining the potential risks and benefits of powdered medical gloves, in the interim the Agency believes the risks that have been identified support a recommended labeling statement advising health care providers and consumers of the risks presented by glove powder.

Therefore, elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability for a draft guidance document entitled "Recommended Warning for Surgeon's Gloves and Patient Examination Gloves That Use Powder." The draft guidance document provides a recommended warning statement for powdered glove labeling that will inform health care providers and consumers of the risks associated with glove powder.

The guidance document, when finalized, will help to address the risks

associated with powdered medical gloves while FDA determines if additional measures, such as a ban, are necessary.

II. Submission of Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Division of Dockets Management (*see ADDRESSES*), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Barbara, J., M. C. Santais, D. A. Levy, *et al.*, "Immunoadjuvant Properties of Glove Cornstarch Powder in Latex-Induced Hypersensitivity," *Clinical & Experimental Allergy*, vol. 33, pp. 106-112, 2003.
2. Malingier, G., S. Ginath, L. Zeidel, *et al.*, "Starch Peritonitis Outbreak After Introduction of a New Brand of Starch Powdered Latex Gloves," *Acta Obstetrica et Gynecologica Scandinavica*, vol. 79, pp. 610-611, 2000.
3. Odum, B. C., J. S. O'Keefe, W. Lara, *et al.*, "Influence of Absorbable Dusting Powders on Wound Infection," *Journal of Emergency Medicine*, vol. 16(6), pp. 875-879, 1998.
4. Stratmeyer, M., "Medical Glove Powder Report," (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm113316.htm>), September 1997.

Dated: February 1, 2011.

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