Compliance Policy Guide
Sec. 335.700 Surgeons' Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure

Guidance for FDA Staff

This document supersedes Sec. 335.700 Surgeons' Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure, dated July 2005

Issued by:
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

March 2011

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance.

I. Introduction:

This CPG provides guidance to FDA staff on the submission of seizure recommendations for medical gloves that exceed the defect levels in 21 CFR 800.20.

FDA's guidance documents, including this 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.

II. Background:

Surgeons' and patient examination gloves have been increasingly relied upon by health care workers as a barrier to the transmission of Human Immunodeficiency Virus (HIV) and other blood and fluid-borne infectious agents. * * In view of the rapid increase in demand for imported and domestically produced gloves, and the public health benefits of further reducing the risk of transmission of HIV and other blood and fluid borne infectious agents, and to better utilize Agency resources, on November 21, 1989, FDA published in the Federal Register proposed rules to insure that *gloves manufactured for medical use and distribution in the United States* are not adulterated. The final rule, *entitled "Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration",* was published on December 12, 1990, at 55 FR 51254. It was amended on December 19, 2006 at

71 FR 75876, with an effective date of December 19, 2008. It is codified at 21 CFR 800.20.*

FDA will collect samples from lots of gloves using the sample sizes and inspection levels in 21 CFR 800.20(c), and test for defects using the test methods in 21 CFR 800.20(b). The sampling inspection plan used by the FDA is derived from *ISO-2859 (the International Organization for Standardization's* standard for "Sampling Procedures and Tables for Inspection by Attributes"), based on general inspection level II, normal inspection, and an acceptable quality level (AQL) of *1.5%* for surgeons' gloves and *2.5%* for patient examination gloves. Single sampling will be used for lots less than or equal to 1200 gloves, while multiple sampling will be used for larger lots.

III. Policy:

Surgeons' gloves and patient examination gloves that contain holes are adulterated devices. Adulteration will be determined on a lot by lot basis for enforcement purposes. *FDA considers a lot of medical gloves to be adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 351(c), when the number of defective gloves found in the tested sample meets or exceeds the applicable rejection number at the 1.5 AQL for surgeons' gloves or the 2.5 AQL for patient examination gloves. See 21 CFR 800.20(c)(3).*

IV. Regulatory Action Guidance:

Lots of surgeons' and patient examination gloves that *are sampled, tested, and rejected using the procedures in 21 CFR 800.20* are subject to administrative and judicial action, such as detention of imported products and direct reference seizure of domestic products. * *

SPECIMEN CHARGES:

"The article of device is adulterated within the meaning of the Act, 21 U.S.C. 351(c), in that its quality falls below that which it purports or is represented to possess because its defect rate exceeds the permissible rate for medical gloves set forth at 21 CFR 800.20."

Sample language for the letter to the U.S. Attorney:

Medical gloves are intended for use by health professionals, such as physicians and dentists, during surgery and routine medical and dental examinations, and by health care technicians and associated workers. All rely on medical gloves as an effective barrier against the transmission and spread of disease and blood and fluid-borne infectious agents. An effective barrier is increasingly essential in light of the current Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome epidemic, and the potential for a pandemic influenza.

We request seizure because analyses of the gloves by the Food and Drug Administration (FDA) shows that their quality falls below that which they purport or are represented to possess because the defect rate of the gloves exceeds the permissible level set forth in 21 CFR 800.20. ___ out of ___ gloves tested were found to leak or contain holes. 21 U.S.C. 351(c).

Material between asterisks is new or revised.

Issued: 05/31/1991
Revised: 03/2011