

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1383]

KMB

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Draft Guidance for Industry on Surveillance and Detention Without Physical Examination of Condoms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Guidance for Industry, Surveillance and Detention Without Physical Examination of Condoms." Many foreign manufacturers and shippers of condoms have consistently failed to provide condoms of adequate quality for distribution in the United States, which presents a potentially serious hazard to health for users. The draft guidance is intended to help industry understand FDA's policy to monitor continuously recidivist firms under our import program. This policy is neither final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of* 11/13/00 *publication in the Federal Register*] .

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance for Industry, Surveillance and Detention Without Physical Examination of Condoms" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

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Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John J. Farnham, Center for Devices and Radiological Health (HFZ-332), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4616.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Surveillance and Detention Without Physical Examination of Condoms." This draft guidance is intended to provide guidance to FDA staff and industry about a recidivist policy for firms that repeatedly attempt to import condoms that violate quality requirements. FDA's experience with sampling, examination, and testing of condoms raises concerns about the barrier properties of some condoms exported to the United States. Our analyses of condoms exported to the United States show a significant variation in the quality of the condoms exported by various manufacturers/shippers. We repeatedly place the same manufacturers/shippers on import detention due to leaks and defects in their condoms. These firms then need to provide us with private laboratory analyses for a number of shipments in order to demonstrate that the quality of the condoms and the firm's manufacturing operations comply with FDA standards. Once the firms provide such evidence, we remove them from import alert. However, many of these same manufacturers/shippers have repeated violative analyses and return to import alert status. This cyclical problem of violations requires continuous auditing and monitoring of recidivist firms to prevent the entry of defective condoms into the United States.

In an attempt to ensure that condoms exported to the United States are in compliance with FDA standards, we revised Import Alert #85-02, "Surveillance (100% Sampling) and Detention

Without Physical Examination of Condoms,” referred to as the “Recidivist Policy.” This initiative was a joint effort between the agency’s Center for Devices and Radiological Health’s Office of Compliance, the Office of Regulatory Affairs’ Division of Import Operations and Policy, and the Office of Chief Counsel.

The Recidivist Policy defines three increasingly stringent compliance levels for firms who have shipped violative condoms to the United States. Levels 1 and 2 allow voluntary compliance opportunities, while Level 3 provides a mechanism to issue a warning letter for apparent violations of the Federal Food, Drug, and Cosmetic Act, including noncompliance with the quality systems regulation for good manufacturing practices. A finding of Level 3 noncompliance will automatically place any future shipments of condoms from the manufacturer/shipper on detention, without the need for FDA to perform an actual inspection at the foreign manufacturer, due to the continued failure of condoms to pass minimum FDA standards upon import.

The agency has adopted good guidance practices (GGP’s), which set forth the agency’s policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a draft Level 1 guidance consistent with GGP’s.

This draft guidance represents the agency’s current thinking on the surveillance and detention without physical examination of condoms. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

II. Electronic Access

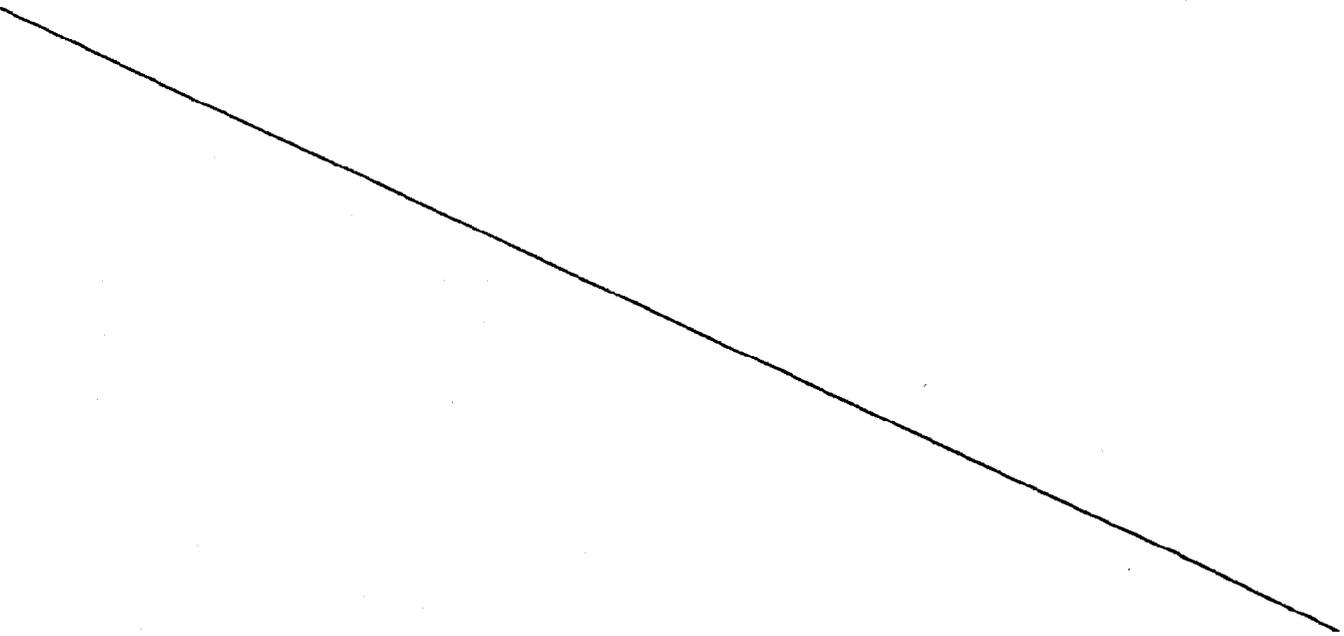
In order to receive the draft guidance entitled “Surveillance and Detention Without Physical Examination of Condoms” via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number

1139 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes various Level 1 guidance documents for comment, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. "Surveillance and Detention Without Physical Examination of Condoms" will be available at <http://www.fda.gov/cdrh/oc/condom1.pdf>.

III. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in



the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/31/00
July 31, 2000

Linda S. Kahan

Linda S. Kahan,
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Center for Devices and Radiological Health.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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