Guidance for Industry

SURVEILLANCE AND DETENTION WITHOUT PHYSICAL EXAMINATION OF CONDOMS

Draft Guidance – Not for Implementation

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Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20857.

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GUIDANCE FOR SURVEILLANCE AND DETENTION WITHOUT PHYSICAL EXAMINATION OF CONDOMS[1]

(Recidivist Policy)

This Recidivist Policy represents the Food and Drug Administration's (FDA) guidance to Agency personnel regarding manufacturers/shippers who continually export defective condoms to the United States.

BACKGROUND

Consumers rely on condoms for protection from HIV (AIDS) and other sexually transmitted diseases (STDs), as well as for contraception. Defective condoms present a potential hazard to health. The Center for Devices and Radiological Health (CDRH) has found that some foreign manufacturers and shippers of condoms consistently fail to provide condoms of adequate quality for distribution into the United States. Therefore, continuous monitoring of these devices is needed.

This draft guidance is intended to provide guidance to FDA staff and industry about a recidivist policy for firms that repeatedly attempt to import condoms that violate quality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

[1] This document is intended to provide guidance. It represents the Agency'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. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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, Office of Regulatory Affairs (ORA), 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 Act, including non-compliance 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.

Legal Charges for Defective Condoms

When there is evidence that shipments of condoms contain defects/holes, they may be refused entry into the United States under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) because they appear to be of substandard quality. This means that these defective condoms are considered adulterated under section 501(c) of the Act. If the defective condoms are labeled for the prevention of disease, then they are also considered misbranded under section 502(a) because the claim is misleading since the devices contain defects/holes and therefore may not effectively prevent disease.

When FDA documents repeated shipments of violative products, the agency may issue the manufacturer or shipper a Warning Letter in accordance with the Recidivist Policy outlined later in this document. This Warning Letter may cite the firm for failure to manufacture the device in conformance with the Quality System Regulation in addition to the charges discussed above. When a pattern of recidivism creates an appearance of violation of the Quality System Regulation, and FDA issues a Warning Letter to a particular firm, FDA may also refuse entry of the condoms manufactured or shipped by that firm under section 801(a)(1) of the Act because the methods, facilities, and controls,

used to manufacture, package, and store the condoms appear to be out of conformance with the Quality System Regulation. (Title 21, Code of Federal Regulations (CFR) Part 820; promulgated under section 502 (f)(i) of the Act.) The condoms therefore appear to be adulterated under section 501(h) of the Act.

Guidance to FDA Field Offices

FDA district offices may detain, without physical examination, all shipments of condoms from manufacturers/shippers listed on FDA's Import Alert #85-02 Attachments A and B. Surveillance sampling of condoms from manufacturers/shippers that do not appear on Import Alert #85-02 Attachments A and B should be performed on each shipment according to the latest guidance.

Because the presence of defects/holes in condoms may present a possible hazard to health, only one (1) defective sample is needed to recommend detention without physical examination to FDA's Division of Import Operations & Policy (DIOP). DIOP has direct authority to detain, without physical examination, any defective condoms without the approval of CDRH. In addition, the subchapter called "Recommendations Based on One Sample" in Chapter 9 of the Regulatory Procedures Manual contains guidance for defective condoms.

Recidivist Policy

The following strategy provides guidance to the field concerning manufacturers/shippers who repeatedly export defective condoms to the United States. Such manufacturers/shippers are identified as "recidivist" firms. Three levels of detention are addressed in the Recidivist Policy as follows:

Level 1 Detention: Firms on Level 1 detention are listed in Attachment A of Import Alert #85-02 and are indicated by an "*" beside their name. These include firms that have failed FDA analysis for the first time, as well as firms that have recently been removed from Level 3.

When a shipment contains defective condoms and is found violative, based on FDA laboratory testing, the shipment should be detained. A recommendation for detention of future shipments without physical examination should be sent to DIOP at HFC-170. Firms will be placed on Import Alert #85-02 only for "condoms." Specific types/styles of condoms (spermicidal, ribbed, contoured etc.) are not considered separate categories for the purposes of the Recidivist Policy and should not be referenced in a recommendation for detention. DIOP will review the recommendation to ensure the

circumstances support detention without physical examination, as discussed in this guidance.

If the recommendation supports detention under the Act, as implemented by the recidivist policy described in this document, the manufacturer/shipper will be placed on Attachment A of Import Alert #85-02 and an "*" will be placed beside the firm name. Any subsequent shipments of condoms from that manufacturer/shipper may be detained without physical examination, including types, styles, or brands of condoms that were not specifically found violative by testing. The manufacturer/shipper may obtain entry of subsequent shipments by presenting evidence that the individual shipments are not adulterated. Evidence may include sample testing performed by an independent laboratory in the United States. The testing performed should follow the sampling plan contained in the current compliance policy guide (CPG 7124.21), and the test methods in the current Laboratory Information Bulletin (LIB) for water leak testing.

In order for the responsible manufacturer/shipper to be removed from Level 1 detention, the firm should provide documentation that contains sufficient evidence to show that its condoms are not adulterated. Evidence which shows that five consecutive condom shipments are non-violative, based on valid analytical methods such as FDA's sampling plans and test methods, may be considered adequate evidence to remove the manufacturer/shipper from Level 1 detention.

Level 2 Detention: Firms on Level 2 detention are listed in Attachment A of Import Alert #85-02 and are indicated by an "**" beside their name. These include firms that fail FDA or private lab analysis while on Level 1 detention, or firms that have a violative shipment within 24 months after being removed from Level 1.

If a manufacturer/shipper currently on Level 1 detention has a sample tested by a private laboratory, and the sample contains defects that cause the shipment to be violative, the district import operations staff at port of entry should notify DIOP and submit supporting documentation. This information enables DIOP to place the firm on Level 2 detention and identify the manufacturer/shipper on Attachment A of Import Alert #85-02 with two asterisks "**".

If a manufacturer/shipper was removed from Level 1 detention, but within 24 months from the date the firm was removed from Level 1 detention, has another violative sample based on FDA laboratory test results, the district at the port of entry should notify DIOP and submit supporting documentation. DIOP will then verify that the manufacturer/shipper was on Level 1 detention during the previous 24 months and, if confirmed, should place the firm on Level 2 detention. The manufacturer/shipper will be identified on Attachment "A" of Import Alert #85-02 with two asterisks "**". DIOP will notify CDRH.

When DIOP places a firm on Level 2 detention, CDRH will notify the foreign firm in writing of the concerns about possible deficiencies in the manufacturing practices and process controls that may be affecting the quality of the condoms shipped to the United States. A copy of the Quality System Regulation for Medical Devices will be attached to the letter for the firm's information (21 CFR part 820).

Before removing a firm from Level 2 detention without physical examination, FDA may need greater assurance that the condoms are not adulterated than that needed for removal from Level 1. Evidence documenting 10 consecutive non-violative shipments, as tested by an independent laboratory in the U.S., may be considered adequate to demonstrate that the firm is shipping condoms to the United States that are not violative. Other types of evidence to remove the appearance of a violation will be evaluated by CDRH on a case-by-case basis.

Level 3 Detention: Firms on Level 3 detention are listed in Attachment B of Import Alert #85-02. These include firms that fail FDA or private lab analysis while on Level 2 detention, or firms that were removed from Level 2 detention, and subsequently have another violative shipment within 24 months from the date FDA either removed the firm from level 1 detention status or increased the status to Level 2 detention. These firms are initially listed in Attachment A of IA #85-02 with three asterisks "***" until CDRH

has issued a Warning Letter to the firm. These firms will be listed on Attachment B of IA #85-02 after the Warning Letter is issued. Firms on Attachment B will not be allowed to enter their condoms into the U.S., and will remain on Attachment B until they demonstrate conformance with the Quality System Regulation. Evidence of conformance with the Quality System Regulation may consist of an inspection by FDA, or certification by the manufacturer of conformance to the Quality System Regulation based on an audit by a qualified third party.

If a manufacturer on Level 2 detention has another violative sample analyzed by an independent testing laboratory in the U.S., the district at the port of entry should notify DIOP and submit supporting documentation. If a manufacturer/shipper that was previously removed from Level 2 detention has another violative sample based on FDA laboratory test results within 24 months from the date FDA either removed the firm from Level 1 detention status or moved the firm to Level 2 detention, the district at the port of entry should notify DIOP and submit supporting documentation. DIOP will notify CDRH.

DIOP and CDRH will verify the manufacturer/shipper has previously been on detention two times during the past 24 months, and, if confirmed, DIOP will place the manufacturer/shipper on attachment "A" with three asterisks (***).

Based on the failure of the manufacturer's/shipper's condoms to pass FDA testing after removal from Level 2 detention, as discussed above, or having failed an independent laboratory test in the U.S. while on Level 2 detention, FDA may issue a Warning Letter to the firm. If supported by CDRH's review of the manufacturer's import and inspection history, this Warning Letter may include an adulteration charge under section 501(h) of the Act for apparent deviations from the Quality System regulation evident by repeated testing failures (see the Legal Charges for Defective Condoms section above).

When a Warning Letter for Quality System deficiencies is issued, DIOP should place the manufacturer/shipper on Level 3 detention by placing the manufacturer/shipper on Attachment B of Import Alert #85-02.

Testing to determine if a shipment is non-violative may not be sufficient to remove the appearance of a violation for manufacturers/shippers on Level 3 detention. Manufacturers/shippers will remain on Level 3 detention until they can demonstrate that the condoms are manufactured in accordance with the Quality System Regulation for Good Manufacturing Practices. The type of evidence that may be considered adequate would include an acceptable FDA on-site inspection of the manufacturing facilities, or a written certification of conformance with the Quality System Regulation provided by the manufacturer/shipper, together with the results of an independent audit performed by a qualified third party.

After the manufacturer/shipper shows that the apparent Quality System regulation deficiencies have been corrected, the manufacturer/shipper will be removed from Level 3 detention and taken off Attachment B, Import Alert #85-02. The manufacturer/shipper then will be placed on Level 1 detention and listed on Attachment A of Import Alert #85-02 with one asterisk "*". Placement on Level 1 indicates the need for individual shipment testing to confirm that the condoms do not contain defects. Adequate evidence to be removed from Level 1 detention, at this point, may be five consecutive shipments that pass independent laboratory testing.

Questions or issues concerning science, science policy, sample collection, testing, preparation, or analytical methodology should be forwarded to the Division of Field Science at (301) 443-3320 or (301) 443-3007.

Questions concerning Compliance Policy Guide 7124.21, condom labeling, or other compliance issues should be forwarded to Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, OB/GYN, Gastroenterology & Urology Branch at (301) 594-4616.

SAMPLING

Sampling should be conducted according to the sampling plan in CPG 7124.21, and the most recent applicable sampling guidance documents.

When an entry consists of various styles of condoms (e.g. unlubricated, lubricated, spermicidally lubricated, ribbed etc.), FDA districts may meet the 100% surveillance requirement of import alert IA #85-02 by sampling only one style from each shipment chosen at the district's discretion. If the district determines that more than one style needs to be sampled, then a separate sample should be taken for each style**. Multiple styles should not be mixed in one sample.**

If only one style of condom is sampled from a shipment that consists of several different styles and the sample fails the water leak test**,** there is an appearance of adulteration and **the entire shipment should be refused entry**. Conversely, if three samples from the same shipment are considered necessary and all fail the water leak test, this counts for **only one failure** under the recidivist policy and only one recommendation for detention.

When taking a sample of a condom style from a shipment that includes numerous boxes/cartons of that style, FDA sample collectors should attempt to open several different cartons in order to obtain a representative sample.