Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Surveillance and Detention Without Physical Examination of Condoms

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. When submitting comments, please refer to Docket No. 00D-1139. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

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Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Surveillance and Detention Without Physical Examination of Condoms

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. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Consumers rely on condoms for protection from HIV (AIDS) and other sexually transmitted diseases (STDs), as well as for contraception. Because condom defects, such as holes, can compromise the effectiveness of the condom barrier and pose a potentially significant hazard to the health of users, FDA samples condoms and performs water leak testing as described in Compliance Policy Guide CPG 7124.21.

FDA's Center for Devices and Radiological Health (CDRH) is aware from its import records that some foreign manufacturers and shippers repeatedly attempt to import condoms that fail water leak testing (i.e., they do not meet the acceptable quality criteria defined in CPG 7124.21, based on the number of defective condoms in the samples). To address the issue, FDA proposed a strategy for import surveillance and detention in the draft guidance made available on August 14, 2000. FDA is making available this final guidance document to provide guidance to FDA staff and industry regarding FDA's strategy for addressing further imports of condoms from manufacturers/shippers[1] whose condoms have failed to meet FDA's minimum acceptable quality criteria.

[1] In this guidance, the terms "manufacturer" and "shipper" refer to an entity whose name and address will be listed on the Import Alert as part of the information to identify the condoms that are subject to detention without physical examination because of an appearance of adulteration. As used in this guidance, the term "firm" refers to an entity

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.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

Legal Basis for Denying Admission of Condoms

FDA may refuse admission of condoms into the United States under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) if it appears from examination that they are adulterated or misbranded (21 U.S.C. 381(a)(3)).

FDA specifically defines sampling plans and adulteration criteria for condoms in Compliance Policy Guide CPG 7124.21. If FDA determines that a sampled shipment of condoms contains an unacceptable level of defects as described in CPG 7124.21, then the shipment appear to be adulterated under section 501(c) of the Act (21 U.S.C. 351(c)), which defines a device as adulterated if its quality falls below that which it purports or is represented to possess.

In addition, repeated shipments of adulterated condoms may present the appearance that the condoms are not manufactured in accordance with the Quality Systems regulation, Title 21, Code of Federal Regulations (CFR) Part 820, which is promulgated under section 520(f) of the Act. When a device appears to be in nonconformance with section 520(f) of the Act, the devices may be refused admission to the United States not only under section 801(a)(3)of the Act (21 U.S.C. 381(a)(3)), but also under section 801(a)(1) (21 U.S.C. 381(a)(1)), which authorizes refusal of admission, "If it appears from the examination of such samples or otherwise that ... the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f)."

Surveillance and Placement on Import Alert #85-02

FDA field 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

providing information to the agency to rebut the appearance of adulteration applicable to particular condoms. This might be the manufacturer/shipper, importer, distributor or other entity.

sampling of condoms from manufacturers/shippers that do not appear on Attachments A and B of Import Alert #85-02 should be performed according to the latest import guidance. (For information regarding sampling, see the "Sampling" section of this document on page 10.)

Because the presence of defects in condoms may present a potentially significant health hazard, one (1) violative sample may be sufficient to recommend detention without physical examination as described in Chapter 9, Section 6 of the FDA Regulatory Procedures Manual 2008 (Import Operations and Actions; Detention without Physical Examination (DWPE)). Therefore, in addition to detaining the violative shipment, the FDA field office at the port of entry should also submit a recommendation for detention of future shipments without physical examination to the Division of Import Operations and Policy (DIOP) at HFC-170.

Condoms from identified manufacturers/shippers should be placed on Import Alert #85-02 under the regulatory classification category "condom" only. Specific types/styles of condoms, such as spermicidal, ribbed, contoured, etc., are not considered separate categories for the purposes of Import Alert #85-02 and should not be referenced in a recommendation for detention. DIOP should review the recommendation to ensure the evidence supports detention without physical examination in accordance with the Act, and that such detention is consistent with the policy expressed in this guidance.

While a manufacturer/shipper is listed on Import Alert #85-02, any subsequent shipments of condoms from the same manufacturer/shipper may be detained without physical examination, including types, styles, or brands of condoms that were not specifically found violative by testing.

Purpose of Import Strategy

This guidance provides a risk-based decision process for managing the Agency's available resources for condoms. FDA's strategy will manage the large volume of condom imports while allowing adequate opportunities for firms to demonstrate that the condoms offered for import conform to FDA's acceptable quality criteria. Accordingly, FDA has devised a risk-based, tiered process for placing condoms from identified manufacturer/shippers on Import Alert #85-02, for releasing individual shipments, and for removing condoms from the identified manufacturers/shippers from the import alert.

Import Strategy

This guidance document describes three levels of import surveillance and detention for condoms from manufacturers/shippers who have offered for import to the United States condoms that do not meet FDA's acceptable quality criteria that appear in CPG 7124.21, as evidenced by failure of FDA or independent private laboratory water leak testing occurring within a manufacturers/shipper's Import Surveillance Cycle (Cycle). A manufacturers/shipper's Cycle begins on the date that it is placed on Level 1 Detention and ends when 24 months have elapsed since the initiation of the Cycle unless condoms from the manufacturers/shipper are placed on Level 3 detention, as described below in this guidance document.

For each level, the guidance explains the criteria for that level, the actions the agency may take regarding import detention and refusal of admission, and what the agency will accept as evidence to demonstrate that the condoms being offered for import meet FDA's minimum acceptable quality criteria.

Determining the Import Detention Level

Routine examination of imports of condoms is conducted in accordance with CPG 7124.21. When such an examination reveals that a shipment of condoms is defective, FDA's enforcement strategy for addressing that shipment and future shipments of condoms from the same manufacturer/shipper will directly relate to the manufacturers/shipper's import history. That history will determine which of three levels of detention is appropriate.

The process used to make this determination is represented graphically in the flow chart provided on page 11. Each stage of the process is cross-referenced with the corresponding flow chart decision, action, and outcome boxes in the discussion below.

Level 1 Detention

Criteria for Level 1 Detention (Flow Chart Decision Box D1):

When DIOP receives a recommendation for detention, they should review the manufacturer/shipper's import history to determine whether:

- The manufacturer/shipper is currently listed on Import Alert #85-04, or
- The manufacturer/shipper has previously been listed on Import Alert #85-04 within an ongoing cycle.

If it is determined that neither of these conditions apply, then Level 1 detention is appropriate. If either condition is applicable, see the "Criteria for Level 2 Detention" and the "Criteria for Level 3 Detention" sections below.

Placement on Level 1 Detention (Flow Chart Action Box L1):

If the DIOP review determines that the manufacturer/shipper has not been listed previously on Import Alert 85-02 during an ongoing Cycle, and that the recommendation supports detention under the Act due to the appearance of a violation, the manufacturer/shipper should be listed on Attachment A of Import Alert #85-02 with a single asterisk ("*") along with the date of listing. In this manner, the date on which the condoms from that manufacturer/shipper are placed on Level 1 detention will initiate the firm's Cycle.

A firm may dispel the appearance of adulteration and obtain admission of subsequent individual shipments of condoms listed on the import alert by presenting evidence to the FDA field office at the port of entry that the individual shipments are not adulterated. Evidence may include sample

testing performed by an independent private laboratory in the United States. The testing performed should follow the sampling plan contained in current CPG 7124.21. For further information on how to submit private laboratory test results to FDA, refer to the Private Laboratory Guidance, found at Volume III, Section 7 of the ORA Laboratory Manual, available at http://www.fda.gov/ora/science_ref/lm/default.htm.

Removal from Level 1 Detention: (Flow Chart Decision Box D4)

To obtain removal of a manufacturer/shipper's condoms from Level 1 detention under this guidance, a firm should provide documentation to DIOP that contains sufficient evidence to show that imported condoms from the identified manufacturer/shipper consistently meet FDA's acceptable quality criteria. Evidence sufficient for removal of a manufacturer/shipper's condoms from Level 1 detention will generally consist of independent private laboratory analyses, using FDA's sampling plans and test methods, showing that a minimum of five consecutive condom shipments meet the FDA acceptable quality criteria. For further information on removal from detention refer to the "Request for Release from Detention" section on page 9 of this document.

Important Note: (Flow Chart Outcome Box O1)

Even when a manufacturers/shipper's condoms have been removed from Level 1 detention, if another shipment of condoms from this same manufacturer/shipper fails analysis during the remainder of the Cycle, FDA should consider the previous placement on Level 1 detention when making further decisions regarding detention of the manufacturer/shipper's imports. (See "Level 2 Detention" below.)

Level 2 Detention

Criteria for Level 2 Detention: (Flow Chart Decision Boxes D1, D2)

When DIOP receives a recommendation for detention, they should review the manufacturer/shipper's import history. If DIOP determines that there is an ongoing Cycle and:

- the manufacturer/shipper was previously listed on Import Alert #85-02, Level 1 Detention, as discussed above ("Criteria for Level 1 Detention") during this Cycle but its condoms were removed from the import alert without advancing to Level 2 Detention, or
- the manufacturer/shipper is currently listed on Import Alert #85-02, Level 1 Detention, and there is further evidence that its condoms are adulterated, such as a violative private laboratory (or FDA) analysis

then DIOP will notify CDRH. CDRH and DIOP will both review the manufacturer/shipper's import history to determine if the evidence supports placing condoms from that manufacturer/shipper on Level 2 detention.

Placement on Level 2 Detention: (Flow Chart Action Box L2)

If the DIOP/CDRH review determines the recommendation supports detention under the Act due to the appearance of a violation and that the criteria for Level 2 detention have been met then the manufacturer/shipper's name should be listed on Attachment A of Import Alert #85-02 with two asterisks ("**") and the date that its condoms were most recently placed on Level 1 detention.

At the same time, CDRH should notify the foreign manufacturer/shipper in writing about possible deficiencies in their manufacturing procedures and practices that may be affecting the quality of the condoms offered for import to the United States. The letter should advise the foreign manufacturer/shipper that continued failure of its condoms to meet FDA's acceptable quality criteria may create an appearance that the manufacturer/shipper's manufacturing process does not satisfy the Quality Systems requirements promulgated under section 520(f) of the Act. Such an appearance would constitute the basis for detention of imports under section 801(a)(1) until FDA receives satisfactory evidence of compliance with the Quality Systems requirements. Manufacturers will be advised that they should review their manufacturing procedures and practices to assure that they are in accordance with the Quality System regulation (21 CFR Part 820). If the review shows that corrections are necessary to ensure condoms of acceptable quality, then such corrections should be made prior to offering further shipments of condoms for entry to the United States. A copy of the Quality System regulation should be attached to the letter for the manufacturer/shipper's information.

A firm may dispel the appearance of adulteration and obtain admission of subsequent individual shipments of condoms from a manufacturer/shipper listed on Import Alert #85-02, Level 2 detention, by presenting evidence to the FDA field office at the port of entry that the individual shipments are not adulterated. Evidence may include sample testing performed by an independent private laboratory in the United States.

Removal from Level 2 Detention: (Flow Chart Decision Box D3)

To obtain removal of a manufacturer/shipper's condoms from Level 2 detention under this guidance, a firm should provide documentation to DIOP that contains sufficient evidence to show that the imported condoms consistently meet FDA's acceptable quality criteria. Due to its increased concerns at Level 2 regarding the ability of the manufacturer/shipper's condoms to meet the FDA criteria, FDA may need greater assurance than is needed for removal from Level 1 detention. Evidence sufficient for removal of a manufacturer/shipper's condoms from Level 2 detention will generally consist of independent private laboratory analyses, using FDA's sampling plans and test methods, showing that a minimum of ten consecutive condom shipments meet the FDA acceptable quality criteria. For further information on removal from detention refer to the "Request for Release from Detention" section on page 9 of this document.

Important Note: (Flow Chart Outcome Box O1)

After DIOP receives adequate evidence, FDA may remove the manufacturer/shipper's condoms from Level 2 detention. However, if another shipment of condoms from this same manufacturer/shipper is found to be defective during the remainder of the Cycle, FDA should consider the history of Level 2 detention when making further decisions regarding detention of the manufacturer/shipper's imports. (See "Level 3 Detention" below.)

Level 3 Detention

Criteria for Level 3 Detention: (Flow Chart Decision Boxes D1, D2)

When DIOP receives a recommendation for detention, they should review the manufacturer/shipper's import history. If DIOP determines that there is an ongoing Cycle and:

- the manufacturer/shipper was listed on Import Alert #85-02, Level 2 Detention, during this Cycle but its condoms were removed from the import alert without advancing to Level 3 Detention,, or
- the manufacturer/shipper is currently listed on Import Alert #85-02, Level 2 Detention, and there is further evidence that its condoms are adulterated, such as a violative private laboratory (or FDA) analysis,

DIOP will notify CDRH. CDRH and DIOP will both review the manufacturer/shipper's import history to determine if the evidence supports Level 3 detention.

Placement on Level 3 Detention: (Flow Chart Action Box L3)

If the DIOP review determines the recommendation supports detention under the Act due to the appearance of a violation and that the Criteria for Level 3 Detention have been met, then the manufacturer/shipper should be listed temporarily on Attachment A of Import Alert #85-02 with three asterisks ("***") until CDRH completes its review of the supporting documents and other relevant information. These documents may include, but are not limited to, results of FDA and private laboratory sample analysis, previous import history, and the status of the current Cycle.

Firms attempting to import condoms that are in this temporary status may request entry of individual shipments based on independent private laboratory testing, conducted in accordance with CPG 7124.21, which indicates the shipment is of acceptable quality.

Placement on Attachment B: (Flow Chart Outcome Box O2)

If the CDRH review finds that the supporting documents and other relevant information presents the appearance that the methods used in, or the facilities or controls used for, the manufacture,

packing or storage of the device at the manufacturer/shipper's facility do not conform to the requirements of section 520(f), then future shipments of the condoms manufactured at that facility may be refused admission pursuant to section 801(a)(1)). CDRH will then notify DIOP that they should list that manufacturer/shipper's facility on Attachment B of Import Alert #85-02 .

At the same time, CDRH should notify the foreign manufacturer/shipper in writing that there is an appearance of nonconformance to the requirements of section 520(f), and that future shipments of the manufacturer/shipper's condoms may be refused admission in accordance with section 801(a)(1) until the manufacturer/shipper provides adequate evidence to rebut this appearance.

Removal from Level 3 Detention (Attachment B):

Test results showing that individual shipments of condoms meet FDA's minimum acceptable quality criteria generally will not be sufficient for removal from Level 3 detention. A history of repeated shipments of defective condoms can present the appearance of nonconformance with good manufacturing practices (section 520(f)). Evidence showing that individual shipments of condoms are of acceptable quality and, therefore, not adulterated under section 501(c), may not be adequate to dispel the appearance of nonconformance with 520(f) because the condoms may have been produced under a manufacturing system that does not conform to good manufacturing practices. The appearance of failure to comply with the requirements of 520(f) provides an independent basis for refusal of admission under section 801(a)(1).

To correct the appearance of violations underlying detention without physical examination for condoms on Level 3 detention, a manufacturer should assess its manufacturing system and correct any systemic problems that underlie the apparent nonconformance with good manufacturing practices. It should demonstrate to FDA/CDRH that the condoms produced at the facility listed on Attachment B are manufactured in accordance with the Quality System regulation. Such evidence should include a FDA on-site inspection of the manufacturing facilities that indicate conformance with the Quality System regulation, 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 demonstrates to CDRH that the apparent systemic manufacturing problems have been corrected and that it is complying with section 520(f), CDRH will request that DIOP remove the manufacturer/shipper's condoms from Level 3, Attachment B. The manufacturer/shipper's condoms then will be placed on Attachment A of Import Alert #85-02 with the statement: "[Firm name] was moved from Attachment B to Attachment A on [date], as the result of an establishment inspection of the firm. Products from this firm remain subject to DWPE. Districts should immediately report violative private laboratory results to DIOP Operations and Policy Branch" to indicate they have been removed from Level 3 but are now in an interim status pending submission of additional evidence to correct the appearance of adulteration under section 501(c) caused by the past violative shipments. While the manufacturer/shipper's condoms are in this interim detention status, FDA may detain shipments of condoms without physical examination. However, firms may obtain entry of individual

shipments by presenting evidence to the FDA field office at the port of entry to rebut the appearance of (501(c)) adulteration, such as independent private laboratory testing of individual shipments to demonstrate that the condoms meet FDA's acceptable quality criteria.

With sufficient evidence, the manufacturer/shipper's products may be removed from this interim status. Evidence sufficient for removal of a manufacturer/shipper's condoms from this interim detention status will generally consist of independent private laboratory analyses, using FDA's sampling plans and test methods, showing that a minimum of five consecutive condom shipments meet the FDA acceptable quality criteria. Removal from the interim detention status, subsequent to removal from Level 3 based on an acceptable FDA or third party inspection, ends the manufacturer/shipper's current Cycle. At this point, a firm may request removal of its condoms from listing on Import Alert #85-02 (and termination of the Cycle) as described in the "Request for Release from Detention" section on page 9 of this document.

If a manufacturer/shipper's condoms are currently on Import Alert #85-02 in interim status and FDA receives further evidence of adulteration, such as a violative analysis from an independent private laboratory (or FDA), the field office at the port of entry should make a recommendation to DIOP for detention. If the DIOP review determines that the recommendation supports detention under the Act due to the appearance of a violation, the manufacturer/shipper should be listed on Attachment A of Import Alert #85-02 with a single asterisk ("*") along with the date of listing. In this manner, the date on which the manufacturer/shipper's condoms are placed on Level 1 detention will initiate a new import surveillance Cycle. Likewise, if a Cycle has ended and a manufacturer/shipper's condoms removed from the Import Alert, but a future shipment of condoms from the same manufacturer/shipper is tested and found to be defective by FDA or an independent private laboratory, the manufacturer/shipper's condoms may again be placed on Level 1, beginning a new Cycle. Once a new Cycle has begun, the import history of the manufacturer/shipper's condoms prior to the beginning of the new Cycle should not be taken into consideration for purposes of determining the import detention level.

Request for Reconsideration of Detention Level

A firm who believes that its condoms have been inappropriately placed on Level 2 or Level 3 detention, may submit evidence to CDRH to rebut this placement.[2] For example, the firm might present evidence that results of analyses indicating defects in its condoms were actually caused by type 1 sampling errors.[3] It might also present evidence that previous defective shipments were found during a previously concluded Cycle, so that a new shipment of defective condoms should result at most in placement on Level 1 detention and initiation of a new Cycle. CDRH will review any such information submitted, in conjunction with the documents relating to the analyses of the condoms in question and evaluate which level of detention, if any, is appropriate.

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[2] Firms who believe their condoms have been inappropriately placed on Level 1 Detention should contact DIOP to attempt to rebut this placement.

[3] Type 1 sampling error is the probability that a sampling plan for attributes will reject a lot when true percent defective is equal to or less than ($\leq$) the Acceptable Quality Level (AQL), where the AQL is equal (=) to the percent defective that a sampling plan for attributes will accept with probability equal (=) to 0.95.

Request for Release from Detention Without Physical Examination

In order for a manufacturer/shipper's condoms to be removed from Attachment A of IA #85-02, FDA should be provided with satisfactory results of sample analyses for a number of consecutive shipments sufficient to demonstrate compliance with FDA requirements. The documentation should consist of

- documentation, including FDA entry numbers showing the FDA release of a number of consecutive entries of the manufacturer's devices sufficient to demonstrate compliance with FDA requirements, (see "Removal from Level 1 Detention" and "Removal from Level 2 Detention") and

- test records (analytical worksheets) from independent qualified U.S. testing laboratories using the FDA analytical worksheet form FDA 431 or equivalent. Testing performed at the manufacturing facility or by private laboratories in the country of origin may not be acceptable due to the potential for rapid degradation of condoms during shipment to the U.S.

Firms may submit the appropriate documentation with a request for their condoms to be removed from the Import Alert and from Detention without Physical Examination to the following office in FDA:

Division of Import Operations and Policy (DIOP)
5600 Fishers Lane (HFC-170)
Rockville, Maryland 20857 USA
Phone: 301-443-6553 Fax: 301-594-0413

If FDA agrees that the results of sample analysis or other evidence submitted demonstrate compliance of the manufacturer/shipper and condoms, then the manufacturer/shipper's condoms will be removed from the Import Alert and no longer subject to Detention Without Physical Examination.

Sampling

Sampling should be conducted according to the sampling plan in CPG 7124.21 and the most recent applicable sampling guidance documents, including Import Alert #85-02.

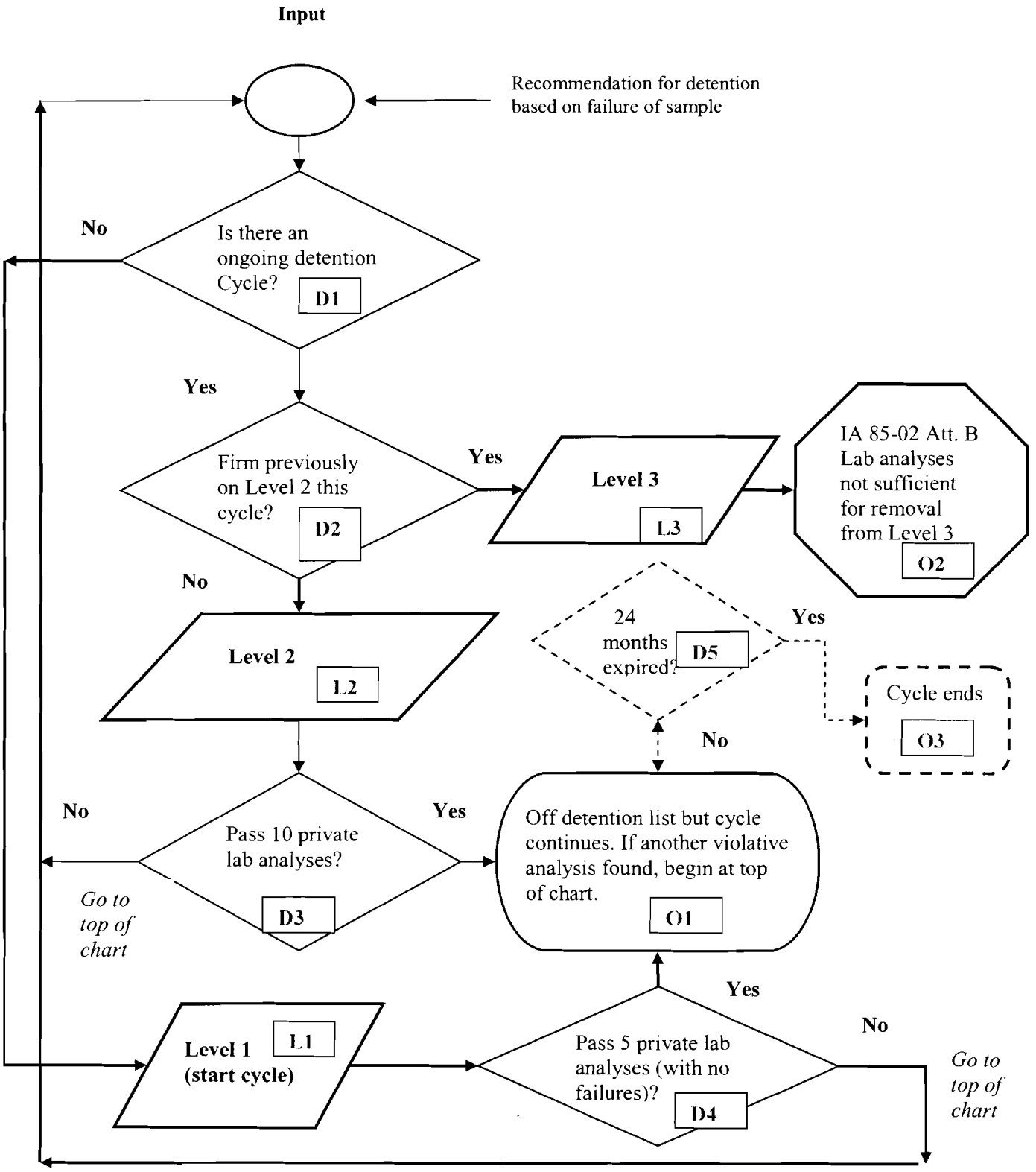
When an FDA field office wishes to sample an entry that includes various styles of condoms (e.g. unlubricated, lubricated, spermicidally lubricated, ribbed etc.), a separate sample should be taken for each style that the field office wishes to test. Multiple styles should not be mixed in one sample.

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 quality acceptance criteria, the shipment constitutes one failure under the current 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 staff should attempt to open several different cartons in order to obtain a representative sample.

Further Information

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) 827-7605 or (301) 827-7606.

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 (240) 276-0115.

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