FOR FURTHER INFORMATION CONTACT: Clara A. Sliva, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–827–0496.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2000, the responsibility for categorization of commercially marketed products under CLIA was transferred from the Centers for Disease Control and Prevention (CDC) to FDA. This allows manufacturers to submit premarket applications for products and requests for complexity categorization of these products under CLIA to one agency. This draft guidance document contains information on the administrative procedures that the manufacturers of in vitro diagnostic products will use to receive a complexity categorization under CLIA from FDA.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the administrative procedures for CLIA categorization of commercially marketed in vitro diagnostic products. 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.

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 guidance document is issued as Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance document entitled ''Guidance for the Administrative Procedures for CLIA Categorization'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at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 (1143) 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Persons interested in obtaining a copy of the draft guidance document may also do so using the Internet. The Center for Devices and Radiological Health (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 ''Guidance for Administrative Procedures for CLIA Categorization,'' 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. The draft guidance document entitled ''Guidance on the Administrative Procedures for CLIA Categorization'' will be available at http://www.fda.gov/cdrh//ode/guidance/1143.pdf

IV. Comments

Interested persons may, on or before November 13, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance document. 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–20464 Filed 8–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0053]

Guidance for Industry on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.'' This guidance document finalizes the agency's policy on how it intends to regulate third parties and hospitals engaged in reprocessing single-use devices (SUD's) for reuse. This guidance document sets forth FDA's priorities for premarket submission requirements, which will be based on the device's Code of Federal Regulations (CFR) classification (i.e., class I, II, and III).

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this 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 brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Larry D. Spears, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 3, 1999 (64 FR 59782), FDA published a proposed strategy on the reuse of SUD's. This proposal identified the steps under consideration in the development of the agency's SUD reprocessing policy. These steps were to: (1) Develop a list of commonly reused SUD's; (2) develop a list of factors to determine the degree of risk associated with reprocessing devices; (3) apply those factors to the list of commonly reprocessed SUD's and categorize them into three categories (high, moderate, and low); and (4) develop priorities for enforcement of premarket submission regulatory requirements for third party and hospital reprocessors, based on the category of risk.

In addition to publishing the proposed strategy document for public comment, FDA also sponsored a teleconference on November 10, 1999, and convened an open public meeting on December 14, 1999 (64 FR 63818,

November 22, 1999), to obtain comments on the proposed strategy. As a result of the comments received, FDA published on February 11, 2000 (65 FR 7027), two companion draft guidances entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme'' and ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.''

The draft guidance entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme'' (the ''RPS guidance'') set forth factors that the agency would consider in categorizing the risk associated with SUD's that are reprocessed. This process, called the Risk Prioritization Scheme, would determine the risk categories for frequently reprocessed SUD's by assigning an overall risk to each SUD based on the risk of infection and the risk of inadequate performance following reprocessing. The three categories of risk were high, moderate, and low. The risk category would then be used to set FDA's enforcement priorities for premarket submission requirements. Appendix 2 of the RPS guidance included a list of frequently reprocessed SUD's and their risk category according to the Risk Prioritization Scheme. Under this proposed guidance document, FDA would consider any reprocessed SUD that was not included on the list to be high risk.

The draft guidance entitled ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' (the ''SUD enforcement guidance'') set forth FDA's priorities for enforcing premarket submission requirements for premarket notifications (510(k)'s) or for premarket approval applications based on the risk categorization of a device as determined by the companion RPS guidance. Premarket submission requirements for SUD's deemed high risk by the Risk Prioritization Scheme would be implemented within 6 months of the issuance of FDA's final guidance document on reuse; within 12 months for moderate risk SUD's; and within 18 months for low risk SUD's. FDA would actively enforce nonpremarket requirements within 6 months of issuance of FDA's final reuse guidance document. FDA received over 150 written comments to the docket on the November 1999 proposed strategy plan and to the February 2000 draft guidances.

FDA received many comments that supported the agency's decision to actively regulate third party and hospital reprocessors and its decision to exclude ''opened-but-unused'' SUD's from this enforcement strategy. FDA also learned that stakeholders and interested parties believed that the Risk Prioritization Scheme lacked clarity and was too subjective. To demonstrate this point, several stakeholders used the scheme to evaluate their products. In all cases the stakeholders' risk category for their devices ranked higher or lower than FDA's risk category for the same devices. Several commentors expressed concern that FDA was imposing burdensome regulations on hospitals. Others were concerned that many hospitals are not prepared to comply with the agency's premarket submission requirements due to their lack of experience in this area or to their limited financial resources. Several stakeholders identified additional SUD's that they were currently reprocessing or were considering reprocessing in the future that were not on FDA's current list of frequently reprocessed SUD's.

As a result of the comments the agency received, FDA has revised the final SUD regulatory strategy as follows:

1. The proposed Risk Prioritization Scheme will not be used to determine the timing of FDA's enforcement priorities for the premarket submission requirements. Rather, FDA will use the device classification listed in the CFR (i.e., class I, class II, or class III) to set its enforcement priorities for the premarket submission requirements.

2. FDA intends to enforce premarket submission requirements within 6 months of issuance of the final SUD enforcement guidance document for all class III devices, within 12 months for class II devices, and 18 months for class I devices. At a later date, FDA intends to examine, on a case-by-case basis, the need to revoke exemptions from premarket requirements for class I and II exempt products based upon the risks that may exist due to reprocessing.

3. For hospital reprocessors, FDA intends to establish a 1-year phase in for active enforcement of the Federal Food, Drug, and Cosmetic Act's (the act's) nonpremarket requirements (e.g., registration, listing, medical device reporting, tracking, corrections and removals, quality system, and labeling). The agency will use the 1-year period following issuance of this final guidance document to educate hospitals about their regulatory obligations. FDA does not anticipate that the 1-year extension of enforcement discretion following issuance of this guidance document will pose any significant public health risks because the agency has no evidence at this time to demonstrate that reprocessing and reuse of SUD's is posing any imminent danger to public health.

4. The ''List of Frequently Reprocessed SUD's'' has been expanded to include additional SUD's that are currently being reprocessed. As noted previously, FDA will use the device classification listed in the CFR to set its enforcement priorities for the premarket submission requirements for all devices. The regulatory premarket submission requirements for reprocessed SUD's that are not included on this list will be based on the device's CFR classification (e.g., class I, II, or III).

As stated in FDA's November 3, 1999, proposed strategy plan on the reuse of SUD's, FDA's primary goal is to ensure a reprocessing and reuse regulatory program based on good science that protects public health, while ensuring that the regulatory requirements are equitable to all parties. FDA does not believe that the changes to its final SUD regulatory strategy pose any significant public health risks. Rather, the agency believes that these changes may facilitate the implementation of the reuse policy by eliminating confusion or misunderstanding regarding a device's risk category and the timing of premarket submissions.

The major change in FDA's plan is the agency's conclusion that it should rely on the traditional device classification scheme rather than the draft Risk Prioritization Scheme to establish its enforcement priorities for the premarket submission requirements. FDA was concerned by comments that stakeholders' interpretation of the Risk Prioritization Scheme resulted in significant differences between the risk category assigned to an SUD by FDA and by the stakeholders. Subjective differences interpreting the Risk Prioritization Scheme could cause some SUD reprocessors to believe that their devices are a lower risk category than FDA's assessment. The agency concluded that disagreements over FDA's risk category for an SUD could cause undue delays in reprocessors complying with the act's premarket submission requirements. The existing CFR device classification system, on the other hand, is an established categorization system that is familiar to all device manufacturers and many device users. Using the CFR device classification system should eliminate problems with the proposed Risk Prioritization Scheme identified by stakeholders.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the regulation of third parties and hospitals

engaged in the reprocessing of SUD's. 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.

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 guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (1168) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the 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 ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,'' 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. ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' is also available at http://www.fda.gov/cdrh/comp/guidance/1168.pdf.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current guidance. 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 guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 31, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–20462 Filed 8–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1383]

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 November 13, 2000.

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.

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