minority status (e.g. co-sponsorship of a publication; co-sponsorship of a Web site or Web-based materials for existing Web sites);

(b) Develop and disseminate a nationwide educational campaign, including advertisements and/or public service announcements (print, TV, and/or radio) to alert individuals and diverse media markets about the dangers of a sedentary lifestyle and to promote co-sponsored programs that might be developed in the course of this initiative. This might include but is not limited to the President's Challenge, a free, motivational tool and recognition program of the PCPFS;

(c) Create, develop, and evaluate effective programs and activities for physical activity, fitness and sports; such programs would provide evidence-based results and best practices;

(d) Co-sponsor the development and management of a CEO/Business round-table to raise awareness of the need for a fit and healthy workforce and to stress the potential role of business in fostering and promoting healthy lifestyles among employees and their families in an effort to reduce chronic disease and health care costs;

(e) Conduct educational and/or practical physical activity, fitness, and/or sports clinics in diverse venues (e.g. after school programs; senior activity centers; parks and recreation centers; others);

(f) Create a ''Road Show'' celebrating 50 years of fitness by providing demonstrations and coaching lessons for all ages that can be continued at the local level;

(g) Sponsor 50th Anniversary memorabilia for distribution at such venues as health fairs, athletic events, special events, and similar occasions;

(h) Sponsor 50th Anniversary special events;

(i) Any combination or enhancement of the above activities;

(j) Other innovative ideas.

Partnership/Co-Sponsorship Agreements

This Partnership Initiative is not a grant or contract award program. Any partnership formed between the Office of the PCPFS and an outside organization will be a voluntary collaboration. Each partner will be responsible for providing the resources necessary to carry out the specified activities of mutual interest contained in the organization's proposal. The Office of the PCPFS will execute, in advance, a concise, written agreement with collaborating partner(s). The partnership/co-sponsorship agreement will identify key elements of the project including: Goals and intended benefits; roles and responsibilities of each partner; resources each plans to commit to the project; any reporting plans; and the time period in which the partnership remains in effect.

Partnership/co-sponsorship agreements will make clear that there will be no Federal endorsement of commercial products or of particular companies. The Office of the PCPFS will have a right to review the use of any Departmental logo and statement related to the Office of the PCPFS programs or materials and products to ensure that they are suitable for the initiative and that government neutrality with respect to commercial products is maintained. When any Departmental logo is approved for use on commercial materials or products that promote the goals and mission of the Office of the PCPFS and its program activities, a disclaimer will be required. The disclaimer must be printed on, or affixed to, commercial partner materials and products and indicate that the use of the logo does not imply any Federal endorsement or warranty of a particular commercial product or of other products of a particular company.

Evaluation Criteria

After engaging in exploratory discussions of potential partnerships and partnership activities, the Office of the PCPFS will make a determination whether the Office of the PCPFS will engage in partnership activities with particular entities and the scope of those activities. The final decision to establish a partnership agreement with an outside organization will be made by the Office of the PCPFS Executive Director. The Office of the PCPFS Executive Director reserves the right to decline partnership opportunities that are not consistent with the Office of the PCPFS goals, mission, or priorities, or for reasons of limited federal resources available to appropriately manage and oversee a proposed partnership. Depending on circumstances, a variety of objective and subjective criteria may be applied. The following factors will be considered when selecting partners and determining the scope of partnership activities:

1. Is the proposed project consistent with the mission and priorities of the Office of the PCPFS and the outside organization?

2. Are the activities proposed by the offering entity likely to provide a substantial public benefit relative to the resources required?

3. Do the potential benefits of the proposed partnership outweigh any potential negative impact on the Department and its ability to accomplish its mission? For example, the Department will avoid any appearance that an offering entity's co-sponsorship of an event would improperly influence the Department or any HHS employee in other official matters in which the offering entity may have an interest. It may be possible to structure a proposal to minimize potential issues.

4. Does the outside entity have the expertise and capacity to carry out its proposed activities?

5. Has the outside entity demonstrated a willingness to work collaboratively with other public and private sector organizations to achieve the stated goals or to advance related efforts, activities, or initiatives?

Organizations that have goals and interests consistent with the mandate of the Office of the PCPFS are encouraged to reply to this notice. Such organizations should have appropriate expertise and resources and be willing to pursue and enhance physical activity, fitness, and/or sports activities within their own organizations. Organizations that meet the criteria are encouraged to reply to this notice.

Working collaboratively with its partners, the Office of the PCPFS and its partners will provide innovative opportunities in diverse venues to improve the adoption and maintenance of regular physical activity for the enhanced health and well-being of all Americans during the 50th anniversary year and beyond.

Dated: November 7, 2005.

Melissa Johnson,

Executive Director, President's Council on Physical Fitness and Sports, Department of Health and Human Services.

[FR Doc. 05–22532 Filed 11–10–05; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0555]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance

entitled ''Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex.'' This draft guidance document describes a means by which natural rubber latex (latex) condoms with and without spermicidal lubricant containing nonoxynol–9 (N–9) may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations for condoms with and without spermicidal lubricant to designate this draft guidance as the special control for latex condoms with and without spermicidal lubricant. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by February 13, 2006. Submit written or electronic comments on the information collection by January 13, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, 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 document.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Farnham, Center for Devices and Radiological Health (HFZ–332), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

SUPPLEMENTARY INFORMATION:

I. Background

The draft special controls guidance document, announced in this document, describes a means by which latex condoms with and without spermicidal lubricant may comply with the requirement of special controls for class II devices. Following is a brief overview of the regulatory history of these devices and an overview of the draft special controls guidance document. The preamble to the proposed rule, which is published elsewhere in this **Federal Register**, provides more detail on the regulatory history of these devices and FDA's examination of condom labeling.

A. Overview of Regulatory History

Condoms are devices that were on the market prior to the enactment of the Medical Device Amendments of 1976 and were intended for contraceptive and prophylactic (preventing transmission of sexually transmitted diseases (STDs)) uses. Condoms are classified at § 884.5300 (21 CFR 884.5300).

Condoms with spermicidal lubricant containing N–9 were introduced to the market after the enactment of the Medical Device Amendments. As discussed in more detail in the preamble to the proposed rule published elsewhere in this **Federal Register**, since 1982, condoms with spermicidal lubricant containing N–9 have been required to bear a contraceptive effectiveness statement to be classified under § 884.5310. This contraceptive effectiveness statement was part of the reclassification order for condoms with spermicidal lubricant on October 29, 1982 (47 FR 49021).

Both condoms and condoms with spermicidal lubricant containing N–9 are classified in class II. Both were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 that broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards to help provide reasonable assurance of the safety and effectiveness of such devices. The notice of proposed rulemaking published elsewhere in this issue of the **Federal Register** proposes to establish this draft guidance document as such a special control. Both condoms and condoms with spermicidal lubricant have also been the subject of specific labeling requirements and recommendations, as discussed next.

In 1987, shortly after the U.S. Surgeon General recommended using a condom for protection against Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS), FDA issued a letter to condom manufacturers with recommendations on condom labeling. This letter was part of a far-reaching public health campaign to inform the American public about AIDS, which was identified in 1981 and associated with HIV and sexual transmission vectors in 1983. The purpose of FDA's 1987 letter was to improve existing condom labeling to better inform condom users about protecting themselves against the spread of HIV/AIDS and other STDs. In 1989, FDA issued a letter further explaining its policy on condom labeling and the necessity of including in the labeling a statement of the condom's intended use(s).

In 1997, FDA published final labeling regulations applicable to latex condoms that address expiration dating and latex sensitivity (§§ 801.435 and 801.437 (21 CFR 801.435 and 801.437)). FDA established expiration dating requirements in response to information that showed that the effectiveness of latex condoms as a barrier to sexually transmitted diseases, including HIV, is dependent upon the integrity of the latex material. The expiration dating regulation of September 26, 1997, addresses the risk of condom deterioration due to product aging and helps ensure that consumers have information regarding the safe use of latex condoms (62 FR 50497 at 50501). The latex sensitivity labeling requirements of September 30, 1997, were added in response to numerous reports of severe allergic reactions and deaths related to a wide range of medical devices containing natural rubber (62 FR 51021 at 51029).

In July 1998, to encourage conformance with condom performance standards, FDA issued a guidance document entitled ''Latex Condoms for Men: Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions,'' which outlined FDA's ''abbreviated review'' approach toward 510(k)s for condoms. To qualify for an abbreviated review, the condom manufacturer must declare conformance to standards recognized by FDA in accordance with section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d). This guidance also carried forward previously issued guidance on suggested labeling for the primary retail package and the package insert, as well as the foil wrapper for individual condoms. In particular, FDA guidance suggested that labeling on the primary package address contraception, and also include the following statement regarding STDs: ''If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.''

This same statement was also recommended for the individual foil wrapper of the condom.

FDA also carried forward a labeling recommendation for the package insert

to include the following expanded version of the previous statement:

If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

In December 2000, Congress enacted Public Law 106–554, which among other provisions, directed FDA to ''reexamine existing condom labels'' and ''determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including [human papillomavirus (HPV)].'' In re-examining condom labeling as directed by Public Law 106–554, and in the development of the draft special controls guidance document, FDA considered the following points:

- Physical properties of condoms;
- Condom slippage and breakage during actual use,
- Plausibility for STD risk reduction attributable to condoms,
- Evaluations of condom effectiveness against STDs by other Federal agencies,
- Clinical data regarding condom protection against STDs,
- Information on N–9 and contraception.

The information FDA considered during the course of its re-examination of the medical accuracy of condom labeling and its analysis support the conclusion that condoms reduce the overall risk of STD transmission, although the degree of risk reduction for different types of STDs varies with their routes of transmission. The preamble to the proposed rule designating this draft guidance as a special control for male condoms made of natural rubber latex, published elsewhere in this **Federal Register**, discusses in detail FDA's review and resulting conclusions, which form the basis for the recommendations made in the draft guidance document.

B. Overview of Guidance

The recommendations in the draft guidance reflect the FDA's re-examination of the medical accuracy of condom labeling, as required by Public Law 106–554. The draft guidance document describes a means by which latex condoms with and without spermicidal lubricant may comply with the requirement of special controls for class II devices. The draft guidance document identifies the issues requiring special controls associated with these devices and recommends addressing these issues through labeling.

The labeling recommendations in the draft guidance are intended to provide information to users of latex condoms with and without spermicidal lubricant. The draft special controls guidance recommends labeling to inform users about the extent of protection provided by condoms against unintended pregnancy and against various types of STDs, as well as information about possible risks associated with exposure to N–9 contained in the spermicidal lubricant of some condoms. The labeling recommendations provide important information for condom users to assist them in determining whether latex condoms are appropriate for their needs and, if so, to determine whether a condom with or without N–9 lubricant is most suitable. FDA believes that this draft guidance is an appropriate special control to help provide reasonable assurance of the safety and effectiveness of latex condoms and latex condoms with spermicidal lubricant containing N–9.

At this time, FDA is not proposing to designate a special control for any condoms made of natural membrane (skin) or synthetic materials. Discussions with the condom industry indicate that condoms made from natural rubber latex represent nearly 98 percent of the U.S. retail market for condoms. The agency understands that all condoms distributed by public health and other organizations are also made from natural rubber latex, based on its discussions with manufacturers. The agency believes, therefore, that the recommendations in the draft special controls guidance document address the vast majority of condoms distributed in the United States. However, at a future date, FDA also intends to address condoms made from other materials that are not specifically addressed by this draft guidance. Until FDA provides further specific guidance for these products, manufacturers of synthetic condoms may consult Part C of FDA's guidance document entitled ''Testing Guidance for Male Condoms Made from New Material (June 25, 1995),'' which is available at *http://www.fda.gov/cdrh/ode/oderp455.html*, and manufacturers of natural membrane condoms may consult the guidance document entitled ''Guidance for Industry-Uniform Contraceptive Labeling (July 23, 1998),'' which is available at *http://www.fda.gov/cdrh/ode/contrlab.html*.

FDA believes, however, that most of the recommendations contained in the draft special controls guidance document for latex condoms regarding labeling to address N–9 are also applicable to nonlatex condoms containing N–9, and encourages manufacturers to follow those aspects, as noted in the draft guidance itself.

The labeling recommendations in the special controls guidance document, when final, will supersede statements in a number of documents, including:

- FDA letter to ''All U.S. Condom Manufacturers, Importers and Repackagers'' (April 7, 1987);
- FDA letter to ''Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention'' (February 13, 1989), which is available at *http://www.fda.gov/cdrh/comp/053.pdf*.
- Contraceptive effectiveness statement required by the 1982 reclassification order for latex condoms with the spermicide, nonoxynol–9, as outlined in an October 29, 1982, **Federal Register** document (47 FR 49201).

If the draft guidance is finalized, FDA intends to withdraw or amend other documents to ensure consistency with the labeling recommendations in the special controls guidance document. Following the finalization of this guidance and the implementation of any final classification rule designating this document as a special control for latex condoms and latex condoms with spermicidal lubricant, labeling for those devices will need to address the issues covered in the final special controls guidance document, unless the device manufacturer in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the agency's current thinking on labeling for male condoms made of natural rubber latex. 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 and regulations.

III. Electronic Access

To receive the draft ''Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1548) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by 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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995 (the PRA)

Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Labeling for Male Condoms Made of Natural Rubber Latex

Description: Under the Medical Device Amendments of 1976 (Public Law 94–295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance.

Both condoms and condoms with spermicidal lubricant containing N–9 are classified in class II. Both were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 (Public Law 101–629) that broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide reasonable assurance of the safety and effectiveness of such devices.

In December 2000, Congress enacted Public Law 106–554, which among other provisions, directed FDA to ''reexamine existing condom labels'' and ''determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases* * *.'' FDA is recommending labeling changes intended to provide important information for condom users, including the extent of protection provided by condoms against various types of STDs.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex. FDA believes that this a one-time burden, because once a label is redesigned, it can be used indefinitely.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
35[2]	34	1,190	12	14,280
3[3]	34	102	12	1,224
Total				15,504

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Current manufacturers for year one.
[3] New manufacturers for years two and three.

The reporting burden hours to respondents in the first year is a one-time burden of 14,280 hours. FDA expects three new manufacturers or repackagers to enter the market yearly, and collectively have a one-time burden of 1,224 hours. The number of respondents and prospective new manufacturers cited in table 1 of this document are based on FDA's database of premarket submissions. The remaining figures were derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 Over-the-Counter (OTC) Human Drug Labeling Requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to redesign the labeling for OTC drugs is an appropriate proxy for the estimated burden to redesign condom labeling.

The latex allergy caution required by § 801.437 and referenced in the draft guidance does not constitute a ''collection of information'' under the PRA. Rather, it is a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)). The expiration dating requirements established by § 801.435 and referenced in the draft guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–22610 Filed 11–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0554]

Revised Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised compliance policy guide (CPG) Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The CPG provides written guidance to FDA's and Customs and Border Protection's (CBP's) staff on enforcement of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States. The CPG has been revised to finalize the sections pertaining to routine shipments of food that are transshipped through the United States, arriving from and exiting to the same country, and regarding the Harmonized Tariff Schedule (HTS) code that is part of the planned shipment information.

DATES: The revised CPG is final upon the date of publication. However, you may submit written or electronic comments on the revised CPG at any time.

ADDRESSES: You may submit comments, identified by Docket No. 2003D–0544 and/ Regulatory Information Number (RIN) number (if a RIN number has been assigned), by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and RIN (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the revised guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

FOR FURTHER INFORMATION CONTACT: Laura Draski, Office of Regulatory Affairs (HFC–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866–521–2297.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 2005 (70 FR 10657), FDA announced the availability of a draft revision to CPG Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This revised guidance was issued with CBP concurrence and explains to FDA and CBP staff the new FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require prior notice to FDA of all food imported or offered for import into the United States (21 CFR parts 1.276 through 1.285). The new policies provide additional flexibility in filing prior notice when, due to the geography, the only practical transportation route available for the shipment is through the United States and when there is a prior notice violation because the prior notice does not include the 6-digit HTS code for the article of food.

FDA received 8 comments on the draft sections of the revised CPG. FDA reviewed and evaluated these comments and has modified the CPG with CBP concurrence, where appropriate.

FDA is issuing this CPG as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents the agency's current thinking on its enforcement policy concerning prior notice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.