Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a neurological embolization device. Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panel/index.html*. Material will be posted on August 4, 2003.

Procedure: On August 5, 2003, from 10:30 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 1, 2003. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:15 a.m. and 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 1, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On August 5, 2003, from 10 a.m. to 10:30 a.m., the meeting will be closed to the public to permit discussion of trade secret and/or confidential information regarding neurological device issues (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 301–594–1283, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 17, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–18635 Filed 7–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 5, 2003, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–573, Ariflo (cilomilast) Tablets, 15 milligrams, by GlaxoSmithKline, for use in chronic obstructive pulmonary disease (COPD).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 2, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 2, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly Littleton Topper at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 17, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–18636 Filed 7–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0263]

Draft Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a level 1 draft guidance entitled ''Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency'' (the draft guidance). This draft guidance presents FDA's general policy for implementing the channels of trade provision in the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: Submit written or electronic comments by September 22, 2003 to ensure adequate consideration in the preparation of the guidance document. Comments on this draft guidance may be submitted at any time. Submit comments on the collection of information by September 22, 2003.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have

Been Revoked, Suspended, or Modified by the Environmental Protection Agency'' to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (CFSAN) (see **FOR FURTHER INFORMATION CONTACT**). Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments concerning the draft guidance and the information collection provisions 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2022, FAX: 301–436–2651, e-mail: *mkashtoc@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On August 3, 1996, the FQPA was signed into law. This law, which amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the act, established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. The Environmental Protection Agency (EPA) is responsible for regulating the use of pesticides (under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)) and for establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the act). EPA, in accordance with the FQPA, is in the process of reassessing the pesticide tolerances and exemptions which were in effect when the FQPA was signed into law. When EPA determines that a pesticide's tolerance level does not meet the safety standard under section 408 of the act (21 U.S.C. 346a), the registration for the pesticide may be canceled under FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities. Under section 408(l)(2) of the act, when the registration for a pesticide is canceled or modified due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture (USDA) has responsibility for monitoring residue levels and enforcing pesticide tolerances in egg products and most meat and poultry products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. FDA would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an ''adulterated'' food. However, the channels of trade provision of the act addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA. The channels of trade provision (section 408(l)(5) of the act) states the following:

> PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF A PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that-
>
> (A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and
>
> (B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;
>
> unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

FDA anticipates that food bearing lawfully applied residues of pesticide chemicals that are the subject of future EPA action the act to revoke, suspend, or modify their tolerances, will remain in the channels of trade after the applicable tolerance is revoked, suspended, or modified. If FDA encounters food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, it intends to address the situation in accordance with this draft guidance. FDA has developed this draft guidance to set forth its policy for how the agency plans to approach its enforcement of the channels of trade provision in the act with respect to pesticide chemicals that are subject to future EPA action to revoke, suspend, or modify their tolerances.

FDA is announcing the availability of this level 1 draft guidance. The draft guidance when finalized, will represent FDA's current thinking on its planned enforcement approach to the channels of trade provision of the act and how such provision relates to FDA regulated products with residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified. 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 the guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of the guidance. The draft guidance is being distributed for comment purposes, in accordance with the FDA's good guidance practices regulation in 21 CFR 10.115(g).

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 in this document.

With respect to the following collection of information, FDA invites comments on: (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: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency

Description: Under the pesticide tolerance reassessment process that EPA was mandated to carry out under the FQPA, EPA is expected to revoke, suspend, or modify tolerances for the pesticide chemicals on various food commodities. Section 408(l)(5) of the act includes a provision, referred to as the ''channels of trade provision,'' that addresses the circumstances under which a food will not be deemed unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA.

In general, FDA anticipates that the party responsible for food found to contain the previously mentioned pesticide chemical residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, suspended, or modified will be able to demonstrate that such food was handled, e.g., packed or processed, during the acceptable timeframes cited in the draft guidance by providing appropriate documentation to the agency as discussed in the draft guidance document. FDA is not suggesting that firms maintain an inflexible set of documents where anything less or different would likely be considered unacceptable. Rather, the agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes.

Examples of documentation which FDA anticipates will serve this purpose consist of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food-processing industries that handle food products that may contain residues of pesticide chemicals after the tolerances for the pesticide chemicals have been revoked, suspended, or modified.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
652	1	652	3	1,956

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA does not know which pesticide chemicals will have their tolerances revoked, suspended, or modified in the future. Instead of calculating the paperwork burden for any one pesticide, FDA calculated the cost for an ''average'' pesticide by looking at test results for 417 pesticide chemicals on domestic products and 450 pesticide chemicals on imported products. FDA then used the average percent of samples found with residues as a substitute for the rate of residues found from a specific pesticide chemical.

The estimated annual reporting burden was determined using the average percent of samples found with residues for all pesticides for domestic and imported products. Using 1999 pesticide monitoring data, domestic products were tested for residues of 417 pesticide chemicals. On average, 1.02 percent of samples tested positive for a given pesticide chemical. For 450 pesticides tested for residues on imported products, on average 2.40 percent of samples contained a given pesticide chemical residue. This rate of positive findings for product samples was applied to the number of potentially affected establishments, 3,730 importers and 23,201 domestic businesses, giving an expected number of 326 potentially-affected businesses per revocation, suspension, or modification of a tolerance. FDA expects this number to be an overestimate of the number of affected businesses for two reasons. One, the positive residue test may be below the new tolerance. Second, tolerances may not be altered for all products. If the tolerance was altered for only vegetables but not fruit, then the number of affected establishments would be smaller. We assume two pesticide tolerances are altered per year, resulting in 652 businesses reporting per year. To date, tolerances have been revoked for two pesticide chemicals. However, FDA expects the total number of pesticide tolerances that are revoked, suspended, or modified by EPA to increase.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Capital Costs
65	1	65	16	1,040	$32,571

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In determining the estimated annual recordkeeping burden, FDA estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or

import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not currently be maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. For firms that do not maintain documentation, such as batch records and inventory records, as part of their normal manufacturing operations, it was estimated that with $500 or less, the necessary software and hardcopy filing systems could be obtained to implement a system.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. 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 draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of this draft guidance is available on the Internet at *http://www.cfsan.fda.gov/guidance.html*.

Dated: July 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–18634 Filed 7–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0282]

Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 8, 2003 (68 FR 40679). The document announced the availability of a guidance entitled ''Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices; Availability.'' The document published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–17135, appearing on page 40679 in the **Federal Register** of July 8, 2003, the following correction is made:

1. On page 40679, in the first column, in the heading of the document, ''[Docket No. 2003D–0232]'' is corrected to read ''[Docket No. 2003D–0282]''.

Dated: July 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–18689 Filed 7–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

New Products and Updated Fee Schedule for National Flood Insurance Program Map and Insurance Products

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This Notice contains several new products and the updated fee schedule for processing requests for the National Flood Insurance Program (NFIP) map and insurance products available through the FEMA Map Service Center (MSC). The changes in the fee schedule include two new products and will allow FEMA to reduce further the expenses to the NFIP by recovering more fully the costs associated with producing, retrieving, and distributing particular NFIP map and insurance products.

DATES: The updated fee schedule is effective for all requests dated, August 1, 2003, or later.

FOR FURTHER INFORMATION CONTACT: Kathy L. Miller, Acting Chief, Information Exchange and Program Evaluation Branch, Mitigation Division, 500 C Street, SW., Washington, DC 20472; by telephone at (202) 646–3316 or by facsimile at (202) 646–4596 (not toll-free calls), by e-mail at *Kathy.Miller@DHS.GOV.*

SUPPLEMENTARY INFORMATION: Throughout this Notice, we use ''we,'' ''our,'' and ''us'' to refer to FEMA.

This Notice contains an updated fee schedule to include two new products available through the MSC.

Effective Date. The updated fee schedule is effective for all written requests, on-line internet requests made through the FEMA Flood Map Store, and all telephone requests received on or after August 1, 2003.

Evaluations Performed. To develop the revised fee schedule for the new products, we first evaluated the actual costs incurred at the MSC for producing, retrieving, and distributing these products. We then analyzed historical sales, cost data, and product unit costs for unusual trends or anomalies; analyzed the effect of program changes, new products, technology investments, and other factors on future sales and product costs. The products covered by this Notice are discussed below.

Periodic Evaluation of Fees. As indicated in the Notice, published at 67 FR 13764, March 26, 2002, a primary component of the fees is the prevailing private sector rates charged to FEMA for labor and materials. Because these rates and the actual production, retrieval, and distribution costs may vary from year to year, we will evaluate the fees periodically and publish a revised fee schedule, when appropriate, as a notice in the **Federal Register**.

Fee Schedule for Requests for Map and Insurance Products

The MSC distributes a variety of NFIP map and insurance products to a broad range of our customers, including Federal, State, and local government officials; real estate professionals; insurance providers; appraisers; builders; land developers; design engineers; surveyors; lenders; homeowners; and other private citizens. Specifically, the MSC distributes the following products:

- Paper (printed) copies of Flood Hazard Boundary Maps (FHBMs);
- Paper (printed) copies of Flood Insurance Rate Maps (FIRMs);
- Paper (printed) copies of Digital Flood Insurance Rate Maps (DFIRMs);
- Paper (printed) copies of Flood Insurance Study (FIS) reports, including the narrative, tables, Flood Profiles, photographs, and other graphics;
- Paper (printed) copies of Flood Boundary and Floodway Maps (FBFMs), when they are included as an exhibit in the FIS;