DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research, Meeting

In accordance with section 10(a)(2) of the Federal advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research.

Times and Dates: 9 a.m.–5 p.m., April 18, 1996; 8:30 a.m.–12 noon, April 19, 1996.

Place: Inn of the Governors, 234 Don Gaspar, Santa Fe, New Mexico 87501.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice and recommendations to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, CDC; and the Administrator, Agency for Toxic Substances and disease Registry (ATSDR), on the establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies. The Committee will take into consideration information and proposals provided by the Department of Energy (DOE), the Advisory Committee for Environment Safety and Health which was established by DOE under the guidelines of a Memorandum of Understanding between HHS and DOE, and other agencies and organizations, regarding the direction HHS should take in establishing the research agenda and in the development of a research plan.

Matters To Be discussed: Agenda items will include: presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health, and ATSDR updates on the progress of current studies; discuss working group recommendations, and public involvement activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Nadine Dickerson, Program Analyst, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: March 27, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Center for Disease Control and Prevention (CDC).

[FR Doc. 96–8118 Filed 4–2–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96C–0097]

Ethicon, Inc.; Withdrawal of a Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 1C0100) proposing that the color additive regulations be amended to provide for the safe use of D&C Red No. 30 (Talc Lake) in cotton sutures.

FOR FURTHER INFORMATION CONTACT: Elke Jensen, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3109.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 26, 1971 (36 FR 12180), FDA announced that a color additive petition (CAP 1C0100) had been filed by Ethicon, Inc., P.O. Box 151, Somerville, NJ 08876–0151. The petition proposed that 21 CFR part 8, now 21 CFR part 74, of the color additive regulations be amended to provide for the certification and safe use of D&C Red No. 30 (Talc Lake) as a dyeing agent for non-absorbable cotton sutures (USP). Ethicon, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: March 26, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–8147 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–01–F

Grassroots Regulatory Partnership Meeting; Southwest Region, Kansas City District Office; Medicated Feed Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Southwest Region, and Center for Veterinary Medicine) is announcing a free public meeting as a followup to a meeting held in April 1995. FDA's Kansas City District Office (Southwest Region) and the Center for Veterinary Medicine will meet with interested persons in the Southwest Region to address specific issues related to the medicated feed industry. The agency is holding this meeting to promote the President's initiative for a partnership approach between front-line regulators and the people affected by the work of the agency.

DATES: The public meeting will be held on Tuesday, April 30, 1996, from 8:45 a.m. to 4:10 p.m.

ADDRESSES: The public meeting will be held at the Holiday Inn, 6111 Fleur Dr., Des Moines, IA 50321.

FOR FURTHER INFORMATION CONTACT: James E. McDonald, FDA Kansas City District Office, P.O. Box 15905, Lenexa, KS 66285–5905, 913–752–2101, FAX 913–752–2111.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnership meetings would be held. Those persons interested in attending this public meeting should FAX their registration including name(s), affiliation, address, telephone and FAX numbers, and any specific questions about the workshop to James E. McDonald (address above), 913–752–2111. There is no registration fee for this meeting. However, due to space limitations, early registration is required. The goal of this meeting is to listen to concerns and ideas, and to identify possible next steps for the agency.

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8167 Filed 4–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0086]

Medical Device Industry Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: FDA is initiating a pilot program in 1996 involving the medical device industry. This pilot program is intended to optimize resource utilization, enhance FDA/industry communication, and provide firms prompt closure to corrected inspectional observations and nonviolative inspections. This pilot program includes eligibility criteria and procedures for preannounced inspections, the annotation of items on form FDA–483–List of Inspectional Observations (FDA 483) with promised or completed corrections, and postinspectional notification to establishments regarding their compliance status.

EFFECTIVE DATE: April 1, 1996.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James L. Dunnie, Office of Regulatory Affairs (HFC–132), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3340, fax 301–827–0929.

SUPPLEMENTARY INFORMATION:

Background

During the recent FDA/medical device industry grassroots forums, several issues were discussed concerning FDA's interaction with the medical device industry. A decision was made to take action on three of the issues discussed. These included instituting: (1) Preannounced inspections, (2) listing promised or completed corrective actions on FDA–483 items, and (3) postinspectional notification to establishments regarding their compliance status.

After considering these issues, the agency decided to initiate a pilot program in fiscal year 1996 involving the medical device industry. This pilot program will occur during the 1996 calendar year and then be formally evaluated. The pilot program will include criteria and procedures for preannounced inspections, the annotation of FDA–483 items with promised or completed corrections, and postinspectional correspondence.

This initiative is currently restricted to inspections of medical device manufacturers that manufacture only medical device products, and not to those products that may cross different program areas like devices/drugs. This initiative may be expanded in the future to other areas after evaluation of the pilot program.

FDA currently maintains contracts with the States of California, Colorado, and Texas to conduct medical device inspections on behalf of FDA. This pilot program will not include those inspections done under State contract for FDA. Noncontract medical device inspections, however, done by FDA personnel in these States, will be eligible for this pilot program.

The purpose of the pilot program is to optimize resource utilization, enhance FDA/industry communication, and provide firms prompt closure to corrected inspectional observations and nonviolative inspections, and inspections in which voluntary action only is indicated.

Implementation of the pilot program will not impact on violative situations because there will not be a decreased level of enforcement, if enforcement is necessary. Previous FDA experience indicates that the overall out-of-compliance rate for preannounced foreign inspections is comparable or even greater than the overall out-of-compliance rate for domestic inspections where preannouncements generally are not made.

This pilot program for preannounced inspections will not affect any of the other current FDA programs that may involve prior inspectional notification.

Preannounced inspections will be offered to those medical device firms that meet the criteria for inclusion in the pilot program. FDA–483 annotations and the postinspectional notification will be done for all medical device inspections during the period of this pilot. The annotations and the notifications are independent of whether the inspection has been preannounced.

The elements of the pilot program are as follows:

I. Preannounced Inspections

A. Basic Premises

1. This pilot program is intended to be applied only to those medical device manufacturers that meet the criteria for consideration.

2. The eligibility of an individual firm for participation in this pilot is at the discretion of the district office using clearly described criteria. (See section I.B. of this document).

3. The implementation of this preannounced inspection program is intended to be flexible, based on appropriate considerations of the agency and firm.

4. The preannouncement should generally be no less than 5 calendar days in advance of the inspection. Should a postponement be necessary, the decision as to the time of rescheduling rests with the investigator/team, but the new inspection date should not exceed 5 calendar days from the originally set date. Inspections may be conducted sooner than 5 calendar days if requested by the firm and if this date is acceptable to the investigator/team.

5. To participate in this program, firms are expected to meet the commitment to have appropriate records and personnel available during the inspection.

6. Preannounced inspections will not limit an investigator's authority to conduct the inspection. Inspections will be as in depth as necessary.

B. Criteria for Consideration

The criteria to be used by the district office to determine whether it is appropriate to preannounce a planned inspection will include:

1. Type of Inspection:

a. Premarket inspections (PMA and 510(k)),

b. Foreign inspections,

c. Medical device bioresearch monitoring inspections,

d. Good manufacturing practice (GMP) inspections of medical device establishments:

- Biennial routine inspections,
- Initial inspections of newly registered establishments,
- Initial inspections of new facilities,
- Initial inspections under new management and/or ownership.

e. NonGMP inspections other than:

- Immediate and urgent responses to complaints,
- Immediate and urgent followup to informant information, and
- Immediate hazard to health recall followup inspections.

f. Recall followup inspections at medical device manufacturers/initial importers (under new regulations, the U.S. designated agent).

2. Eligibility Criteria:

a. GMP inspections of firms with nonviolative histories (inspections classified as no action indicated (NAI) or voluntary action indicated (VAI)). For VAI, adequate corrections of conditions observed and listed on FDA–483 during the previous inspection were verified and did not lead to any further agency action.

b. To remain eligible for preannounced inspections, firms must have a history of having individuals and/or documents identified in previous preannounced inspections reasonably available at the time of the inspection.

C. Procedures

1. The investigator designated to conduct the inspection will contact or, if unavailable at the time of the call, leave word for the most responsible individual at the facility.

2. Changes in dates should be kept to a minimum. If a change is made, a new date should be provided as soon as possible that will facilitate the inspection and accommodate the investigator's schedule.

3. Preannouncements are normally limited to the investigator (or lead investigator for a team inspection) informing the firm of an upcoming inspection. Usually it will be appropriate to inform the firm as to the purpose, estimated duration, and the

number of agency personnel expected to take part in the inspection. The products or processes to be covered should also be described if this will facilitate and be consistent with the objectives of the inspection.

4. When known, specific records/personnel will be requested at the time the inspection is scheduled.

D. Criteria for Assessing the Success of the Preannounced Inspections

1. Office of Regional Operations (ORO) will provide a questionnaire to be completed by district personnel for each of the inspections made under this pilot program. The districts will be responsible for tracking the responses to each of the questionnaires. An end of the calendar year survey of the districts will be conducted by the Division of Emergency and Investigational Operations (DEIO)/Investigations Branch.

2. Industry groups and involved firms will have an opportunity to provide their opinions and recommendations for improvement after FDA has had some experience with the pilot program, through such possible mechanisms as a customer satisfaction survey.

3. CDRH will be asked to provide comments.

4. Comments received in response to this notice will be considered.

II. FDA–483 Annotations

A. Basic Premise

1. In this pilot program for all medical device establishments, the investigator will annotate FDA–483 at the time of issuance to acknowledge an establishment's promised or completed corrective action. Industry should review the annotations on this issued FDA–483 to ensure that there are no misunderstandings on promised corrective actions.

2. A reportable item will not be deleted from FDA–483 because the establishment has promised or completed a corrective action.

The investigator will continue to have the latitude to delete the observation if the establishment's response to the observation clearly shows that the observation is in error or to clarify the observation based on additional information provided.

3. FDA investigators will continue to report only significant observations on FDA–483 and to discuss these and other less significant observations with the establishment's management.

B. Procedures

1. Investigators and analysts will discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when FDA–483 is issued. This discussion will include those observations that are potentially written FDA–483 items or oral observations. Industry should use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made as soon as possible during the inspection process. Investigators are encouraged to verify the establishment's completed corrective action as long as the verification does not unreasonably extend the duration of the inspection.

2. Where practical, FDA–483 observations should include the number of records of a given type examined, for example, ''Two out of 50 records examined were * * *.''

3. If the establishment has promised and/or completed a corrective action to an FDA–483 observation prior to the completion of the inspection, all copies of FDA–483 should be annotated (either following each observation or at the end of FDA–483) with one or more of the following comments, as appropriate:

Item # _____ reported corrected but not verified.

Item # _____ corrected and verified.

Correction of items _____, _____ and _____ promised by 00/00/96.

4. If an observation made during a prior inspection is noted as not being corrected or is a reoccurring observation, it is appropriate to note this on FDA–483.

5. All corrective action taken by the establishment and verified by FDA should be discussed in detail in the establishment inspection report and reported using the Corrective Action Reporting Systems (CARS).

C. Criteria for Assessing the Success of FDA–483 Annotations

1. ORO will provide a questionnaire to be completed by district personnel for each of the inspections made under this pilot program. The districts will be responsible for tracking the responses to each of the questionnaires. An end of the calendar year survey of the districts will be conducted by the DEIO/Investigations Branch.

2. Industry groups and involved firms will have an opportunity to provide their opinions and recommendations for improvement after FDA has had some experience with the pilot program, through such possible mechanisms as a customer satisfaction survey.

3. CDRH will be asked to provide comments.

4. Comments received in response to this notice will be considered.

III. Postinspectional Notification

A. Basic Premise

1. During this pilot program FDA will issue additional postinspectional notification to establishments regarding their compliance status.

2. The two new categories under which firms will receive postinspection notification are:

a. NAI situations where no FDA–483 was issued or only limited, less significant violations were reported.

b. VAI situations where an FDA–483 was issued but all profile classes were found acceptable. In this circumstance, no regulatory action is contemplated based on the inspection.

3. The postinspectional notification letters that are issued under this pilot program will be mailed under the signature of the district director, in that district in which the establishment is located.

4. For those inspectional followups where regulatory action is being considered, FDA's existing modes of notification will continue to be used.

B. Criteria for Assessing the Success of Postinspectional Notification

1. ORO will provide a questionnaire to be completed by district personnel for each of the inspections made under this pilot program. The districts will be responsible for tracking the responses to each of the questionnaires. An end of the calendar year survey of the districts will be conducted by the DEIO/Investigations Branch.

2. Industry groups and involved firms will have an opportunity to provide their opinions and recommendations for improvement after FDA has had some experience with the pilot program, through such possible mechanisms as a customer satisfaction survey.

3. CDRH will be asked to provide comments.

4. Comments received in response to this notice will be considered.

[The following is an example of a letter intended to be issued in situations classified as NAI where no FDA–483 was issued, or only limited less significant violations were reported:]

Date:
Name:
Address:
Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's (description) facility at (address) on (date). The inspection covered the products described below.

(list of products and their profile classes)

The areas inspected appear to be in substantial compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

Based on these findings, the agency is prepared to endorse applicable pending premarket (PMA) submissions or export certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address good manufacturing practices (GMP's) in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits, to ensure you are continuing to maintain conformance with GMP's.

For further information, please contact the following individual at this office:

(name and telephone number)

Sincerely,

[The following is an example of a letter intended to be used in situations classified as VAI where an FDA–483 was issued, but all profile classes were found to be acceptable. This type of letter should be issued only when no regulatory action is contemplated, including issuing a warning letter:]

Date:

Name:

Address:

Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's (description) facility at (address) on (date). The inspection covered the products described below.

(list of products and their profile classes)

While some adverse practices/conditions were observed during the inspection, they do not appear to warrant consideration of regulatory followup at this time. These problems were reported to you on an FDA–483 (copy enclosed) issued at the conclusion of the inspection. The problems should be corrected and we encourage you to advise us as to your followup actions.

Based on these findings, the agency is prepared to endorse applicable pending premarket (PMA) submissions or Export Certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address good manufacturing practices (GMP's) in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits, to ensure you are continuing to maintain conformance with GMP's.

For further information, please contact the following individual at this office:

(name and telephone number)

Sincerely,

Enclosures: FDA–483

Interested persons may, on or before June 3, 1996, submit comments to the Dockets Management Branch (address above). Two copies 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. Received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8185 Filed 3–29–96; 4:05 pm]

BILLING CODE 4160–01–F

[Docket No. 96N–0025]

Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a voluntary pilot program to test the feasibility of using third-party reviews to improve the efficiency of the agency's review of premarket notifications for medical devices. To implement the pilot program, FDA is announcing simplified agency procedures and practices to process premarket notifications (510(k)'s) submitted by, and with a review prepared by, third-party review organizations (third parties). In its discretion, FDA will select third parties pursuant to the general statements of policy with respect to competence and freedom from conflicts of interest announced in this document. FDA recognizes that it has long been common practice for some firms to engage third parties to make a preliminary review and assist in the quality control of documents prior to their submission in 510(k)'s. FDA believes a similar third-party effort may be useful to improve the efficiency of the agency's review process. The pilot program will allow FDA to evaluate the feasibility of using the results of a third party's review in lieu of the agency's initial review effort. This action is part of efforts in pursuit of the reinventing Government goals of the National Performance Review.

DATES: The pilot program will begin August 1, 1996, and will run for a 2-year period. FDA will apply the pilot program procedures to 510(k)'s received during this period from recognized third parties. FDA is now accepting applications for recognition of prospective third parties and will continue to do so through June 3, 1996. To help prospective third parties prepare these applications, FDA will hold an information session for prospective third parties on April 15, 1996, to review the third-party recognition process and criteria described in this notice, and to answer related questions.

Submit written comments on the pilot program by June 3, 1996.

Submit written comments on the information collection requirements by June 3, 1996. At FDA's request, the Office of Management and Budget (OMB) authorized emergency processing of this information collection. OMB approved the information collection for 90 days, under OMB control no. 0910–0318.

ADDRESSES: Prospective third parties should submit an application for recognition, in duplicate, to the Division of Small Manufacturers Assistance (HFZ–220), ATTN: Third-Party Recognition, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 1–800–638–2041 or 301–443–7491, both at ext. 105, or FAX 301–443–8818. 510(k)'s reviewed by third parties should be submitted to the Document Mail Center (HFZ–401), ATTN: Third-Party Review, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

Written comments regarding the pilot program and the information collection requirements may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

Persons interested in attending the information session for prospective third parties should obtain registration information as soon as possible. Copies of a facsimile containing this