

commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) specifies the information that a firm must submit to FDA to obtain a temporary marketing permit. The information required in a temporary marketing permit application under § 130.17(c) enables the agency to monitor the manufacture, labeling, and

distribution of experimental packs of food that deviate from applicable definitions or standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(l) specifies the information that a firm must submit

to FDA to obtain an extension of a temporary marketing permit.

In the **Federal Register** of June 8, 1999 (64 FR 30524), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
130.17(c)	3	1	3	25	75
130.17(l)	4	2	8	2	16
Total					91

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

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received from October 1, 1995, through September 30, 1998, and information from firms that have submitted recent requests for temporary marketing permits.

Dated: August 25, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices 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: Ophthalmic Devices Panel of the Medical Devices 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 23, 1999, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Lincoln Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, or by e-mail at smt@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 23, 1999, from 8:30 a.m. to 1:30 p.m., the committee will hear formal presentations followed by public participation in a discussion of keratomes. Public participants in the group discussion are requested to develop a comprehensive list of problems associated with keratomes, the related causes, and the steps that can be taken to mitigate the problems. From 1:30 p.m. to 5 p.m., the committee will discuss issues related to defining the scope and purpose of a proposed keratome guidance to be developed from an outline of contents currently recommended for keratome premarket notification submissions. Single copies of the outline are available to the public by contacting the person noted above.

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 7, 1999. Formal oral presentations from the public will be scheduled between approximately 9:15 a.m. and 10:15 a.m. on September 23, 1999. Those desiring to make formal oral presentations should notify the contact person before September 10, 1999, 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. Those desiring to be a participant in the open group discussion should notify the contact person by September 10, 1999, to reserve a place at a discussion table.

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

Dated: August 23, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRBC (C1).