Information Line for up-to-date information on this meeting.

Agenda: On February 5, 2004, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a phakic intraocular lens for the reduction or elimination of myopia in adults.

On February 6, 2004, the committee will discuss, make recommendations and vote on a PMA for a radiofrequency electrosurgical corneal shaping device for the temporary treatment of presbyopia. Background information for each day's topic, including the attendee list, 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/panelmtg.html*. Material for the February 5, 2004, session will be posted on February 4, 2004; material for the February 6, 2004, session will be posted on February 5, 2004.

Procedure: On February 5, 2004, from 9 a.m. to 5 p.m., and on February 6, 2004, from 9:30 a.m. to 4:30 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 January 26, 2004. On February 5, 2004, formal oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. Near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. On February 6, 2004, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. Near the end of committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 26, 2004, 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 February 6, 2004, from 8 a.m. to 9:30 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information relevant to pending and future device submissions for vitreoretinal, surgical and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting will be closed to permit discussion of this information (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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: January 5, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–601 Filed 1–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0002]

Draft Guidance for Industry and FDA Staff; Saline, Silicone Gel, and Alternative Breast Implants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Saline, Silicone Gel, and Alternative Breast Implants.'' This version of the draft guidance document updates preclinical, clinical, and labeling recommendations described in ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants'' dated February 11, 2003. The update is based on the latest scientific and medical information on breast implants, and clarifies the type and amount of scientific data that should be submitted to allow FDA to evaluate whether these devices are safe and effective. The draft guidance document contains new recommendations for manufacturers submitting applications for premarket approval of breast implants. Some of the recommendations apply to all premarket approval applications for breast implants, while others are specific to the type of implant. The draft guidance document is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by April 12, 2004.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Saline, Silicone Gel, and Alternative Breast Implants'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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: Samie Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 139.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is revising the guidance document entitled ''Saline, Silicone Gel, and Alternative Breast Implants'' to clarify the type and amount of scientific data that should be submitted to allow FDA to evaluate whether these devices are safe and effective. The draft guidance document provides updated information based on the latest scientific and medical information on breast implants. The draft guidance document contains new recommendations for manufacturers submitting applications for premarket approval of breast implants. Some of the recommendations apply to all premarket approval applications for these devices, while others are specific to silicone gel-filled, saline-filled, or alternative implants. The proposed changes are primarily to the mechanical data, clinical data, and labeling sections of the draft guidance document. In addition, a new section entitled ''Modes and Causes of Rupture'' has been added

that describes the type of data FDA recommends a manufacturer provide to address this issue (this section replaces the previous Retrieval Study section). When final, this draft guidance document will supersede ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants,'' dated February 11, 2003.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Saline, Silicone Gel, and Alternative Breast Implants.'' 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 ''Saline, Silicone Gel, and Alternative Breast Implants,'' you may either send a fax request to 301–443–8818 to receive a paper copy of the document, or send an e-mail request to *GWA@CDRH.FDA.GOV* to receive a paper copy or an electronic copy. Please use the document number (1239) to identify the guidance you are requesting.

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 cleared submissions, 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

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in Sections 3 through 10 of the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB No. 0910–0231). The labeling provisions addressed in Section 11 of the guidance document have been approved under OMB No. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before April 12, 2004. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 7, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–658 Filed 1–12–04; 12:00 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

Agency Information Collection Activities: Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; National Interest Waivers; Supplemental Evidence to I–140 and I–485.

The Department of Homeland Security, Bureau of Citizenship and Immigrations Services (CIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty day until March 15, 2004.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* National Interest Waivers; Supplemental Evidence to I–140 and I–485.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* No Agency Form Number; File No. OMB–22 Bureau or Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households. The information collected via the submitted supplemental documentation will be used by the Bureau of Citizenship and Immigration Services to determine eligibility for the request national interest waiver and to finalize the request for adjustment to lawful permanent resident status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 8,000 responses at one (1) hour per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 8,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or a additional information, please contact Richard A. Sloan (202) 514–3291, Director, Regulations and Forms Services Division, Department of Homeland Security, 425 I Street, NW., Room 4304, Washington, DC 20536. Additionally, comments and/or