This final guidance document, ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations,'' explains for PMA applicants the administrative process FDA intends to follow in its review of the PMA manufacturing section information and the inspection of the particular manufacturing facility and its manufacturing operations. This final guidance document supersedes the corresponding draft guidance issued on June 19, 2006 (71 FR 35275 through 35276).

The comment period for the draft guidance document closed on September 18, 2006. During the comment period, we received several comments and recommendations. Two comments recommended that the agency inspect pilot manufacturing operations or the manufacture of a surrogate product in lieu of inspecting the complete manufacturing operation described in the PMA manufacturing section. FDA disagrees with this recommendation as the statute does not provide such an alternative. The statute requires the agency to determine whether the manufacturing operations, as described in the PMA, conform to good manufacturing practice requirements.

Several comments recommended clarification of certain terms related to the process involved with scheduling inspections and factors that affect the PMA manufacturing section review process. The agency incorporated many of the suggested clarifications.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations.'' 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1566 to identify the guidance you are requesting.

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

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB Control Number 0910–0231; and the collections of information in 21 CFR part 820 have been approved under OMB Control Number 0910–0073.

V. Comments

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

Dated: December 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–126 Filed 1–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0228]

Guidance for Industry and Food and Drug Administration Staff; The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program.'' This guidance provides premarket approval application (PMA) applicants with information about the bioresearch monitoring (BIMO) review process. This includes a BIMO evaluation of clinical and nonclinical information in the PMA and certain PMA supplements as well as preapproval BIMO inspections. The procedural information outlined in this document should help applicants and FDA to better understand the BIMO review and inspection so it can proceed in a timely manner.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program'' 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 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Matthew J. Tarosky, Center for Devices

and Radiological Health (HFZ–300), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0243.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) was signed into law. Among other things, MDUMFA authorized the collection of user fees to improve the performance and predictability of FDA's device review program, including premarket approval applications (PMAs). One such goal included a commitment to improve the scheduling and timeliness of PMA preapproval inspections. A portion of the user fees collected under MDUFMA will be used to help to cover the costs associated with the bioresearch monitoring (BIMO) program review of a PMA and the performance of any related clinical or nonclinical inspections. This final guidance document supersedes the corresponding draft guidance entitled ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program,'' which was announced in the **Federal Register** on June 20, 2006 (71 FR 35436 through 35437).

The comment period for the draft guidance closed on September 18, 2006. During this time, FDA received one set of comments from a device manufacturer concerning the draft guidance. Some of the comments suggested combining the BIMO and manufacturing preapproval inspections. FDA did not make changes in response to these comments because preapproval BIMO and manufacturing inspections can not be performed at the same time. Compared to the preapproval manufacturing inspection program, the BIMO program has different objectives, usually involves inspections of different sites, and FDA investigators with different expertise. FDA did modify the guidance to respond to comments that requested further information about criteria for selecting inspection sites and determining when followup actions are necessary.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program.'' 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1602 to identify the guidance you are requesting.

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*.

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V. Comments

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

Dated: December 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–143 Filed 1–7–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Announcement of an Independent Scientific Peer Review Panel Meeting on the Murine Local Lymph Node Assay; Availability of Draft Background Review Documents; Request for Comments

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Meeting announcement and request for comments.

SUMMARY: NICEATM in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces an independent scientific peer review panel meeting to evaluate modifications and new applications for the Murine Local Lymph Node Assay (LLNA). The LLNA is an alternative test method that can be used to determine the allergic contact dermatitis potential of chemicals and products. The panel will review the following:

- The validation status of three modified LLNA test method protocols that use non-radioactive probe chemicals.
- The validation status of a LLNA limit dose procedure.
- The use of the LLNA to test mixtures, aqueous solutions, and metals (applicability domain for the LLNA).
- The use of the LLNA to determine potency (potential for causing allergic contact dermatitis).
- Revised draft recommended performance standards for the LLNA.

At this meeting, the panel will peer review the draft background review documents and revised draft LLNA performance standards for each topic and evaluate the extent that established validation and acceptance criteria have been appropriately addressed. The panel will also comment on the extent