competent human intervention on a case-by-case basis to medical software devices and has noted two problems that arise. First, some manufacturers have brought to market medical software devices that are actually accessories to classified medical devices without a premarket submission, most likely because of confusion over which devices were meant to be covered by the draft policy. Components, parts, or accessories to classified devices are regulated according to the class of the parent device and are not covered by the draft policy. Second, the increasing complexity and sophistication of current software devices makes it increasingly difficult to decide when healthcare practitioners can, in fact, comprehend the functions performed by the software sufficiently to know when significant errors have occurred.

FDA is, therefore, reassessing its position regarding the regulation of medical software devices. Further, it is important that any exemption from regulatory oversight continue to be based upon an assessment of the risk to human health, as provided by law. Additionally, FDA believes that increased application of proper engineering practices provides an opportunity to develop preproduction controls for the majority of medical software devices which may obviate the need for premarket submissions for such medical software devices in some cases.

II. Purpose and Tentative Agenda of the Workshop

The purpose of the workshop is to obtain information on subjects such as: (1) Definitions that could be used in the classification of medical software devices; (2) criteria that could be used to define risk categories; (3) the scope and content of a proposed software quality audit that might be used in lieu of premarket notification for certain medical software devices; (4) factors related to the unique characteristics of the distribution of software that the agency could consider in determining whether a particular medical software product is intended by the manufacturer or sponsor for commercial distribution; and (5) potential scenarios and regulatory hurdles to implementing a risk-based classification process. This will provide FDA with information to better assess the risks to public health associated with different types of medical software devices.

Presiding over the workshop will be: Harvey Rudolph, Acting Deputy Director, Office of Science and Technology, Center for Devices and Radiological Health, and Harold Schoolman, Deputy Director for Education and Research, NLM. They will be assisted by other FDA and NLM officials.

Opening remarks will be made by representatives of the sponsoring institutions, FDA and NLM, identifying the respective agency's interests in medical software devices. Following these presentations, FDA will make a presentation outlining its responsibilities for regulating medical software devices and for identifying specific areas where information from the public could be most useful. Following FDA's presentation, a specific period of time will be provided for other participants to make presentations. There will be break-out sessions following these presentations where discussion can take place on specific topics, such as those noted above.

Interested persons who wish to present prepared comments at the plenary session to the public workshop may, on or before August 5, 1996, submit to the Dockets Management Branch (address above) a written notice of participation identified with the docket number found in brackets in the heading of this document, including name, address, telephone number, business affiliation, and a brief summary of the presentation. The limited time available will allow 10 minutes or less for each presentation.

FDA requests that individuals or groups having similar interests consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. A schedule of the allotted times will be available at the workshop. Each participant will be notified before the workshop of the approximate time of his or her presentation. The schedule will be placed on file in the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this document. The workshop will also include an opportunity for interested persons who did not submit a notice of participation to make brief statements or comments, if time permits.

The workshop is informal; however, no participant may interrupt the presentation of another participant.

Dated: July 9, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–17880 Filed 7–12–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0221]

Alcon Laboratories, Inc.; Premarket Approval of Acrysof® Models MA60BM and MA30BA Ultraviolet-Absorbing Soft Acrylic Posterior Chamber Intraocular Lenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Alcon Laboratories, Inc., Fort Worth, TX, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Acrysof® Models MA60BM and MA30BA ultraviolet-absorbing soft acrylic posterior chamber intraocular lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 22, 1994, of the approval of the application.

DATES: Petitions for administrative review by August 14, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Donna L. Rogers, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION: On May 28, 1993, Alcon Laboratories, Inc., Fort Worth, TX 76134–2099, submitted to CDRH an application for premarket approval of Acrysof® Models MA60BM and MA30BA ultraviolet-absorbing soft acrylic posterior chamber intraocular lenses. The devices are posterior chamber intraocular lenses and are indicated for replacement of the human lens to achieve visual correction of aphakia in patients 60 years of age and older when extracapsular cataract extraction or phacoemulsification are performed. These lenses are intended for placement in the capsular bag.

On May 20, 1994, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On December 22, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 14, 1996, file with the Docket Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in the brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 21, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–17825 Filed 7–12–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0200]

Bayer Corp.; Premarket Approval of Technicon Immuno 1® PSA Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bayer Corp., Tarrytown, NY, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Immuno 1® PSA Assay. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 22, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 14, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On June 27, 1995 Bayer Corp., Tarrytown, NY 10591, submitted to CDRH an application for premarket approval of Immuno 1® PSA Assay. This device is an in vitro diagnostic device intended to quantitatively measure prostate specific antigen (PSA) in human serum on the Technicon Immuno 1® system. PSA values obtained should be used as an aid in the management (monitoring) of prostate cancer patients. This diagnostic method is not intended for use on any other system.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory Committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On December 22, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 14, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).