Policy and Research, Executive Office Center, 2101 East Jefferson Street, Suite 601, Rockville, Maryland. 20852, (301) 594–1445.

Dated: July 8, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–17879 Filed 7–12–96; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 90F–0063]

Henkel Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to future filing, of a food additive petition (FAP 0B4194) proposing that the food additive regulations be amended to provide for the safe use of a mixed ester product resulting from the reaction of pentaerythritol and dipentaerythritol with C_{14}-C_{22} fatty acids as a release agent for ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers, polyethylene phthalate polymers, and poly(tetramethylene terephthalate) intended to contact food.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 15, 1990 (55 FR 9772), FDA announced that a food additive petition (0B4194) had been filed by Henkel Corp., Organic Products Division, 300 Brookside Ave., Ambler, PA 19002, (Currently c/o Bruce A. Schwemmer, Bruce EnviroExcel Group, Inc., 94 Buttermilk Bridge Rd., Washington, NJ 07882). The petition proposed to amend the food additive regulations in § 178.3860 *Release agents* (21 CFR 178.3860) to provide for the safe use of a mixed ester product resulting from the reaction of pentaerythritol and dipentaerythritol with C_{14}-C_{22} fatty acids as a release agent for ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers, polyethylene phthalate polymers, and poly(tetramethylene terephthalate) intended to contact food. Henkel Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: June 25, 1996.

Alan M. Rulis,

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

[FR Doc. 96–17826 Filed 7–12–96; 8:45 am]

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[Docket No. 86D–0380]

Medical Devices; Medical Software Devices; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) and the National Library of Medicine (NLM) are announcing a public workshop to discuss definitions of medical software devices, criteria for defining risk categories, software quality audits and premarket notification, commercial distribution of software, and the options available for regulating medical software devices. FDA has noted some confusion among manufacturers regarding which requirements apply to medical software devices and accessories. This workshop will help to clarify the requirements, and provide FDA with information to better assess the risks to public health associated with different types of medical software devices.

DATES: The workshop will be held on September 3 and 4, 1996, from 9:30 a.m. to 4:30 p.m. Participants and other persons who want to present data or information must be present by 9 a.m. Written notices of participation must be submitted on or before August 5, 1996.

ADDRESSES: The workshop will be held at the National Institutes of Health, Natcher Conference Center, 45 Center Dr., Bethesda, MD 20892. Written comments, identified with the docket number found in brackets in the heading of this document, regarding the subjects being discussed at the workshop may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. A more detailed listing of the workshop topics, issues, background information, as well as registration forms, can be obtained after August 1, 1996, through the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system. To receive the public workshop on medical software devices documents to your FAX machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number, 1072, followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. The information will be sent by FAX. All workshop-related information can also be obtained by using the World Wide Web. FDA's home page address may be accessed at http://www.fda.gov.

FOR FURTHER INFORMATION CONTACT: Charles S. Furfine, Center for Devices and Radiological Health (HFZ–143), 12720 Twinbrook Pkwy., Rockville, MD 20852, 301–443–2536, ext. 16; FAX 301–443–9101; or EMail csf@fdadr.cdrh.fda.gov.

Registration forms should be sent to Charles Furfine (address above). There is no registration fee but advance registration is required. Interested persons are encouraged to register early because space is limited. If you have a disability that affects your attendance at, or participation in, this meeting, please contact Charles S. Furfine (address above) in writing and identify your needs. The availability of appropriate accommodations cannot be assured unless prior written notification is provided.

SUPPLEMENTAL INFORMATION:

I. Background

On September 25, 1987 (52 FR 36104), FDA published a notice of availability of a ''Draft Policy Guidance for Regulation of Computer Products,'' which the agency was making available for comment. The guidance was intended to provide software developers and manufacturers of medical devices with guidance about which software products were regulated as medical devices and which might be exempt from particular regulatory controls, such as premarket notification. A 1989 draft of the FDA software policy reiterated the basic statements of the 1987 draft, but also addressed specific issues related to blood-bank software products. The 1989 draft also addressed the issue of which medical software devices should be exempt from general controls, including the current good manufacturing practice regulations. The agency stated in the 1989 draft that medical software devices (unclassified medical software devices that are not components, parts, or accessories to classified devices) would not be subject to active regulatory oversight if they ''are intended to involve competent human intervention before any impact on human health occurs (e.g., where clinical judgment and experience can be used to check and interpret a system's output) * * *.''

Since 1989, FDA has gained experience in applying the criterion of

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]

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[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.