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 has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).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]

BILLING CODE 4160–01–F

[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