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FOR FURTHER INFORMATION CONTACT:

Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 9B4658) has been filed by Goldschmidt Chemical Corp., 914 East Randolph Rd., Hopewell, VA 23860. The petition proposes both to amend the food additive regulations in part 177 (21 CFR part 177) by adding a new section and to amend § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of silicone acrylate resins produced by addition of ω -hydroxyalkenes and/or propenyloxy-2,3-dihydroxypropane, mono- or diester with acrylic acid, acetic acid or other saturated monocarboxylic acid, to dimethyl polysiloxane, methylhydrogen polysiloxane, or dimethyl-methylhydrogen polysiloxane as coatings or components of coatings on polymers and on paper and paperboard intended for contact with food. The following optional adjuvants may also be required in the manufacture of silicone acrylate resins: 2-hydroxy-2-methyl-1-phenyl-1-propanone and/or oligomeric 2-hydroxy-2-methyl-1-[4-(1-methylvinyl)phenyl]-1-propanone.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 2, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.
[FR Doc. 99-15877 Filed 6-22-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The FDA Review Process for New Product Applications: An Interactive Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

The Food and Drug Administration (FDA), Los Angeles District, in cosponsorship with the Orange County Regulatory Affairs Discussion Group (OCRA) is announcing the following workshop: The FDA Review Process for New Product Applications: An Interactive Workshop, which is intended to give the medical products industry (drugs, biologics, and medical devices) an opportunity to learn and discuss the process by which the centers and district offices review new product applications. Reviewing staff from the Centers for Biologics, Devices, and Drugs will make presentations regarding the elements of submissions that make the review process more efficient.

Date and Time: The workshop will be held on July 12 and 13, 1999, from 7:30 a.m. to 5 p.m.

Location: The workshop will be held at the Irvine Marriott, 18000 Von Karman Ave., Irvine, CA, 949-553-0100.

Contact: Sandi Velez, Los Angeles District Office, Food and Drug Administration, 19900 MacArthur Blvd., Irvine, CA 92612-2445, 949-798-7748 or FAX 949-798-7715, for further information including a registration form.

Registration: Space is limited. Preregistration and confirmation are required. Registration forms can be obtained at the OCRA web site "http://www.ocra-dg.org" or from Sandi Velez at the numbers given previously. There is a \$250 registration fee if postmarked by June 30, 1999 (\$275 after July 1, 1999) payable to OCRA. The registration fee and form should be sent to PeriAnn DiRocco at OCRA Submissions Conference, 5405 Alton Pkwy., suite 5A-624, Irvine, CA 92604, FAX and voice 949-348-9141, and received no later than July 7, 1999. The registration fee will cover actual expenses incurred by OCRA including refreshments, lunch, materials, parking fees, and speaker expenses.

If you need special accommodations due to disability, please contact Sandi Velez at least 7 days in advance.

Dated: June 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99-16091 Filed 6-21-99; 2:29 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-263]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* On Site Inspection for Durable Medical Equipment (DME) Supplier Location & Supporting Regulations in 42 CFR, 424.57; *Form Nos.:* HCFA-R-263 (OMB# 0938-0749);

Use: To identify and implement measures to prevent fraud and abuse in the Medicare program. Controlling the entry of suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) to Medicare has been identified as one of the most effective ways to prevent fraud and abuse. To meet this challenge, HCFA is moving forward with a plan to improve the quality of the process for enrolling and reenrolling DMEPOS suppliers into the Medicare program by enhancing procedures for verifying supplier information collected on the Form HCFA 855S (DMEPOS Supplier Enrollment Application, OMB Approval No. 0938-0685). This form will be used