Dated: February 26, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–6533 Filed 3–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–0459]

Exxon Co. International; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Exxon Co. International has filed a petition proposing that the food additive regulations be amended to provide for the safe use of isopropyl laurate in surface lubricants used in the manufacture of metallic articles intended for contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 9B4647) has been filed by Exxon Co. International, 200 Park Ave., Florham Park, NJ 07932–1002. The petition proposes to amend the food additive regulations in § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) to provide for the safe use of isopropyl laurate in surface lubricants used in the manufacture of metallic articles intended for contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a 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: February 26, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–6528 Filed 3–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–0345]

UCB Films PLC; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that UCB Films PLC has filed a petition proposing that the food additive regulations be amended to provide for the safe use of mono- and bis-(octadecyldiethyleneoxide)phosphates as components of coatings on cellophane intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 9B4642) has been filed by UCB Films PLC, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 177.1200 *Cellophane* (21 CFR 177.1200) to provide for the safe use of mono- and bis-(octadecyldiethyleneoxide)phosphates as components of coatings on cellophane intended for use in contact with food.

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: February 26, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–6526 Filed 3–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 22 and 23, 1999, 8 a.m. to 5 p.m.

Location: Pook's Hill Marriott, Ballroom, 5151 Pook's Hill Rd., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 22, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 21–071, Avandia™ (rosiglitazone, SmithKline Beecham) for the treatment of hyperglycemia in type 2 diabetes mellitus, as monotherapy and in combination with metformin. On April 23, 1999, the committee will discuss the safety and efficacy of NDA 21–073, Actos™ (pioglitazone, Takeda Pharmaceuticals) to improve glycemic control in patients with type 2 diabetes mellitus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 14, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 14, 1999, and

submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C., app. 2).

Dated: March 3, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–6531 Filed 3–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0317]

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

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* State Medicaid Eligibility Quality Control (MEQC) Sampling Plan and Supporting Regulations in 42 CFR 431.800–431.865; *Form No.:* HCFA–317 (OMB# 0938–0146); *Use:* MEQC is operated by the State Title XIX agency to monitor and improve the administration of its Medicaid system. The MEQC system is based on monthly State reviews of Medicaid cases identified through statistically reliable statewide samples of cases selected from the eligibility files. These reviews are conducted to determine whether or not the sampled cases meet applicable State Title XIX eligibility requirements. The reviews are also used to assess beneficiary liability, if any, and to determine the amounts paid to provide Medicaid services for these cases.; *Frequency:* Semi-annually; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 55; *Total Annual Responses:* 110; *Total Annual Hours:* 2,640.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer:

OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235 Washington, D.C. 20503

Dated: March 9, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–6548 Filed 3–17–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–262]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the PRA of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. Due to the fact that the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, we are requesting an emergency review. This collection is necessary to ensure compliance with section 1852 and 1854 of the Balanced Budget Act (BBA). The Plan Benefit Package (PBP) implements the BBA provisions and the regulations, HCFA–1030–FC (which establishes the Medicare+Choice (M+C) program). Under Part C of the Social Security Act (ACT), an M+C organization is required to submit an Adjusted Community Rate Proposal (ACRP), which includes the ACR (Document Identifier: HCFA–R–228) and the PBP (Document Identifier: HCFA–R–262) no later than May 1 of each calendar year. Without emergency approval, entities interested in participating in the M+C program will not be afforded enough time to participate in the PBP prior to the 05/01/1999 time period. (This pilot test is intended to ensure reasonable usability of the reporting tool.) As a result, public harm could occur because eligible individuals may not receive the M+C health insurance options stipulated by the BBA. We need to implement by 05/01/1999 so we can evaluate the results of the pilot and proceed with our plan to implement the PBP for the Plan Year 2001. In order to obtain this goal our time table is as follows: obtain emergency PRA approval for the pilot test by April 1999; evaluate, modify, and submit the revised PRA package by August 1999; receive OMB approval by February 2000; in order to meet the deadline for distribution of ACRP instructions by March 2000 for the contract year 2001.

The PBP will be implemented as a pilot project for Plan Year 2000 ACRP submissions, in addition HCFA requires plans to submit PBP's for Plan Year 2001. The PBP tool collects plan level information, replaces the Benefits Information File (BIF), and standardizes