

Drug	Application Number
Cipro (ciprofloxacin) for Suspension	20-780
Allegra-D (fexofenadine hydrochloride/pseudoephedrine hydrochloride) Tablets	20-786
Cardizem (diltiazem hydrochloride) for Injection	20-792
Floxin (ofloxacin) Solution	20-799
Fortovase (saquinavir) Capsules	20-828
Prograf (tacrolimus) Capsules	50-708
Prograf (tacrolimus) Capsules	50-708/S-008
Helidac (bismuth subsalicylate tablets, metronidazole tablets, and tetracycline hydrochloride capsules)	50-719
Cellcept (mycophenolate mofetil) Tablets	50-723
Amphotec (amphotericin B) Cholesteryl Sulfate for Injection	50-729
Zithromax (azithromycin) for Injection	50-733
Idamycin-PFS (idarubicin hydrochloride) Injection	50-734
Neoral (cyclosporine) Capsules	50-735
Neoral (cyclosporine) Solution	50-736
Neoral (cyclosporine) Capsules	50-737
Neoral (cyclosporine) Solution	50-738
Omnicef (cefdinar) Capsules	50-739
Ambisome (amphotericin B) Liposome for Injection	50-740
Stromectol (ivermectin) Tablets	50-742
Bactroban (mupirocin calcium) Cream	50-746
Omnicef (cefdinir) Suspension	50-749
Primsol (trimethoprim hydrochloride) Solution	74-374/S-002

As part of its review of each of the NDA's and supplements listed in this table, FDA reviewed an EA. In each instance, FDA found that the approval of the NDA or supplement will not significantly affect the human environment. In accordance with the Council on Environmental Quality regulations in 40 CFR 1501.4(e) and FDA regulations in § 25.41, FDA prepared a FONSI for each NDA and supplement. This notice announces that the EA's and FONSI's for these human drug products may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. For a fee, copies of these EA's and FONSI's may be obtained by writing the Freedom of Information Staff (address above). The request should identify by the application number the EA's and FONSI's requested. Separate requests should be submitted for each application number. Additional information regarding the submission of freedom of information requests is available on the Internet at <http://www.fda.gov/opacom/backgrounders/foiahand.html>.

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0486]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 11, 1997 (62 FR 65274), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

OMB has now approved the information collection and has assigned OMB control number 0910-0045. The approval expires on April 30, 2001.

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-339]

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

AGENCY: Health Care Financing Administration.

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;