application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the application under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining ophan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers. FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	0	0	0	0	0
316.20, 316.21, and 316.26	90	1.78	160.20	125	20,025
316.22	5	1	5	2	10
316.27	5	1	5	4	20
316.30	450	1	450	2	900
316.36	.2	3	.6	15	9
Total Burden Hours	.....	.....	.....	.....	20,964

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 5 years, that 90 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (§§ 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to require an average of 95 hours of professional staff time and 30 hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13042 Filed 5–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0286]

Environmental Assessments and Findings of No Significant Impact

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reviewed environmental assessments (EA's) and issued findings of no significant impact (FONSI's) relating to the 167 new drug applications (NDA's) and supplemental applications listed in this document. FDA is publishing this notice because Federal regulations require public notice of the availability of environmental documents.

ADDRESSES: The EA's and FONSI's may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, or a copy may be requested by writing the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5629.

SUPPLEMENTARY INFORMATION: Under the National Environmental Policy Act of 1969 (NEPA), Congress declared that it will be the continuing policy of the Federal Government to ''use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic and other requirements of present and future generations of Americans.'' (See 42 U.S.C. 4331(a).) NEPA requires all Federal agencies to include in every proposal for major Federal actions significantly affecting the quality of the human environment, a detailed statement assessing the environmental impact of, and alternatives to, the proposed action and to make available to the public such statements. (See 42 U.S.C. 4332, 40 CFR 1506.6, and 21 CFR 25.51(b).)

FDA implements NEPA through its regulations in part 25 (21 CFR part 25). Under those regulations, actions to approve NDA's, abbreviated new drug applications (ANDA's), and supplements to existing approvals ordinarily require the preparation of an EA. (See § 25.20(l).)

FDA approved 167 NDA's and supplemental NDA's and ANDA's for the products listed in the following table:

Drug	Application Number
Klonopin (clonazepam) Tablets	17–533/S–023
Ativan (lorazepam) Injection	18–140/S–003
Rythmol (propafenone hydrochloride) Tablets	19–151/S–002
Novantrone (mitoxantrone hydrochloride) for Injection	19–297/S–014
Actigall (ursodiol) Capsules	19–594/S–016
Humatrope (somatropin) for Injection	19–640/S–013 and S–018
Asacol (mesalamine) Tablets	19–651/S–005
Tilade (nedocromil sodium) Inhalation Aerosol	19–660/S–015
Zoladex (goserelin acetate) Implant	19–726/S–018
Prilosec (omeprazole) Capsules	19–810/S–036
Soriatane (acitretin) Capsules	19–821
Zoloft (sertraline hydrochloride) Tablets	19–839/S–002 and S–011
Corlopam (fenoldopam mesylate) for Injection	19–922
Zofran (ondansetron hydrochloride) Tablets	20–103/S–005
Astelin (azelastine hydrochloride) Nasal Spray	20–114
Migranal (dihydroergotamine mesylate) Nasal Spray	20–148
Lovenox (enoxaparin sodium) Injection	20–164/S–008
Nicoderm (nicotine) Transdermal	20–165/S–011
Imdur (isosorbide mononitrate) Tablets	20–225
Normiflo (ardeparin sodium) Injection	20–227
Tegretol-XR (carbamazepine) Tablets	20–234
Lescol (fluvastatin sodium) Capsules	20–261/S–012
Junior Strength Advil (ibuprofen) Tablets	20–267
Genotropin (somatropin) for Injection	20–280/S–008
Coreg (carvedilol) Tablets	20–297/S–001
Kytril (granisetron hydrochloride) Tablets	20–305
Nizoral A–D (ketoconazole) Shampoo	20–310
Agrelin (anagrelide hydrochloride) Capsules	20–333
Famvir (famciclovir) Tablets	20–363/S–012
Niaspan (niacin) Tablets	20–381
Zanaflex (tizanidine hydrochloride) Tablets	20–397
Zofran (ondansetron hydrochloride) Injection	20–403
Avita (tretinoin) Cream	20–404
Lanoxin (digoxin) Tablets	20–405
Prevacid (lansoprazole) Capsules	20–406/S–010 and S–011
Gastromark (ferumoxsil) Suspension	20–410
Genesa (arbutamine hydrochloride) Injection	20–420
Orgaran (danaparoid sodium) Injection	20–430
Pulmicort (budenoside) for Inhalation	20–441
Imodium A–D (loperamide hydrochloride) Tablets	20–448
Pandel (hydrocortisone buteprate) Cream	20–453
Galzin (zinc acetate) Capsules	20–458
Nasalcrom (cromolyn sodium) Nasal Spray	20–463
Nasacort AQ (triamcinolone acetonide) Nasal Spray	20–468/S–002
Zyflo (zileuton) Tablets	20–471
Retin–A Micro (tretinoin) Gel	20–475
Vanceril (beclomethasone dipropionate) Inhalation Aerosol	20–486
Alphagen (brimonidine tartrate) Solution	20–490
Fareston (toremifene citrate) Tablets	20–497
Transderm Scop (scopolamine) Transdermal	20–501
Hydrochlorothiazide Capsules	20–504
Topamax (topiramate) Tablets	20–505
Aphthasol (amlexanox) Paste	20–511
Lupron Depot (leuprolide acetate) for Injection	20–517/S–002
Retrovir (zidovudine) Tablets	20–518
Loprox (ciclopirox) Gel	20–519
Condylox (podofilox) Gel	20–529
Duract (bromfenac sodium) Capsules	20–535
Norplant II (levonorgestrel) Implant	20–544
Flovent (fluticasone propionate) for Inhalation	20–549
Valtrex (valacyclovir hydrochloride) Caplets	20–550/S–003
Fosamax (alendronate sodium) Tablets	20–560/S–003
Quadramet (samarium sm–153 lexidronam pentasodium) for Injection	20–570
Flomax (tamsulosin hydrochloride) Capsules	20–579
Cotazym (pancrelipase) Capsules	20–580
Follistim (follitropin) for Injection	20–582
Depacon (valproate sodium) Injection	20–593
Tazorac (tazarotene) Gel	20–600
Junior Strength Motrin (ibuprofen) Tablets	20–601
Zofran (ondansetron hydrochloride) Solution	20–605
Imodium (loperamide hydrochloride/simethicone) Tablets	20–606
Arthrotec (diclofenac sodium/misoprostol) Tablets	20–607

Drug	Application Number
Dovonex (calcipotriene) Solution	20–611
Pytest (C–14 urea) Capsules	20–617
Betoptic Pilo (betaxolol hydrochloride/pilocarpine hydrochloride) Suspension	20–619
Copaxone (copolymer–1) for Injection	20–622
Anzemet (dolasetron mesylate) Tablets	20–623
Anzemet (dolasetron mesylate) Injection	20–624
Imitrex (sumatriptan) Nasal Spray	20–626
Meridia (sibutramine hydrochloride monohydrate) Capsules	20–632
Levaquin (levofloxacin) Tablets	20–634
Levaquin (levofloxacin) Injection	20–635
Seroquel (quetiapine fumarate) Tablets	20–639
Gabitril (tiagabine hydrochloride) Tablets	20–646
Diastat (diazepam) Gel	20–648
Edex (alprostadil) for Injection	20–649
Teslascan (mangafodipir trisoodium) Injection	20–652
Alora (estradiol) Transdermal	20–655
Sporanox (itraconazole) Solution	20–657
Requip (ropinirole hydrochloride) Tablets	20–658
Butenafine Hydrochloride Cream	20–663
Dostinex (cabergoline) Tablets	20–664
Diovan (valsartan) Capsules	20–665
Mirapex (pramipexole) Tablets	20–667
Lexxel (enalapril maleate/felodipine) Tablets	20–668
Zagam (sparfloxacin) Tablets	20–677
Clinimix E Sulfite-free (amino acid with electrolytes in dextrose with calcium) Injection	20–678
Ortho Tri-Cyclen (norgestimate/ethinyl estradiol) Tablets	20–681
Glyset (miglitol) Tablets	20–682
Alesse (ethinyl estradiol/levonorgestrel) Tablets	20–683
Lumenhance (manganese chloride tetrahydrate) Solution	20–686
Patanol (olopatadine hydrochloride) Solution	20–688
Posicor (mibefradil dihydrochloride) Tablets	20–689
Aricept (donepezil hydrochloride) Tablets	20–690
Serevent (salmeterol xinafoate) for Inhalation	20–692
Sporanox (itraconazole) Capsules	20–694
Raxar (grepafloxacin hydrochloride) Tablets	20–695
Effexor XR (venlafaxine hydrochloride) Capsules	20–699
Muse (alprostadil) Suppository	20–700
Crinone (progesterone) Gel	20–701
Lipitor (atorvastatin calcium) Tablets	20–702
Claritin EZ (loratadine) Tablets	20–704
Rescriptor (delavirdine mesylate) Tablets	20–705
Emadine (emedastine difumarate) Solution	20–706
Skelid (tiludronate disodium) Tablets	20–707
Lupron Depot (leuprolide acetate) for Injection	20–708
Paxil (paroxetine hydrochloride) Suspension	20–710
Zyban (bupropion hydrochloride) Tablets	20–711
Carbatrol (carbamazepine) Capsules	20–712
Nicotrol (nicotine) for Inhalation	20–714
Vicoprofen (hydrocodone bitartrate/ibuprofen) Tablets	20–716
Prelay (troglitazone) Tablets	20–719
Rezulin (troglitazone) Tablets	20–720
Aldara (imiquimod) Cream	20–723
Femara (letrozole) Tablets	20–726
Uniretic (moexipril hydrochloride/hydrochlorothiazide) Tablets	20–729
Clinimix Sulfite-free (amino acid in dextrose) Injection	20–734
Teveten (eprosartan mesylate) Tablets	20–738
Baycol (cerivastatin) Tablets	20–740
BSS (balanced salt) Solution	20–742
Noritate (metronidazole) Cream	20–743
Tilade (nedocromil sodium) Inhalation Solution	20–750
Crinone (progesterone) Gel	20–756
Avapro (irbesartan) Tablets	20–757
Irbesartan/hydrochlorthiazide Tablets	20–758
Trovan (trovafloxacin mesylate) Tablets	20–759
Trovan (alatrovafloxacin mesylate) Injection	20–760
Nasonex (mometasone furoate) Nasal Spray	20–762
Propulsid Quicksolv (cisapride) Tablets	20–767
Zomig (zolmitriptan) Tablets	20–768
Viracept (nelfinavir mesylate) for Solution	20–778
Viracept (nelfinavir mesylate) Tablets	20–779

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.

[FR Doc. 98–13045 Filed 5–15–98; 8:45 am]

BILLING CODE 4160–01–F

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.

[FR Doc. 98–13044 Filed 5–15–98; 8:45 am]

BILLING CODE 4160–01–F

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;