The information is used by the agency to determine the need for, or desirability of, the requested action and also to determine if the submitted information is sufficient to support the action. FDA determines whether or not to grant the petition based on the information submitted.

The affected respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit institutions or groups.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	120	1	120	12	1,440

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

The agency bases this estimate of burden on fiscal year 1995 data in which there were 120 petitions filed that each took an estimated 12 hours to complete.

Dated: April 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–10779 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0138]

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 141 new drug applications (NDA's), abbreviated new drug applications (ANDA'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, 301–594–5721.

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 25.41(b).)

FDA implements NEPA through its regulations in part 25 (21 CFR part 25). Under those regulations, actions to approve NDA's, ANDA's, and supplements to existing approvals ordinarily require the preparation of an EA. (See § 25.22(a)(8) and (a)(14).)

FDA approved 141 NDA's, ANDA's, and supplemental NDA's for the products listed in the following table:

Drug	Application Number
Coumadin (warfarin sodium) for Injection.	09–218/S–077 and S–078
Tavist-1 (clemastine fumarate) Tablets.	17–661/S–048
Tavist-D (clemastine fumarate/phenylpropanolamine hydrochloride) Tablets.	18–298/S–024
Eulexin (flutamide) Capsules.	18–554/S–014
Nicorette (nicotine) Chewing Gum.	18–612/S–022, 20–066/S–004
Depakote (divalproex sodium) Tablets.	18–723/S–020
Calcijex (calcitriol) Injection.	18–874/S–007
Etodolac (Iodine) Capsules.	18–922/S–013
Heparin Sodium in 5% Dextrose I.V. Infusion.	19–339/S–011, S–012, S–013, and S–014
Prinivil (lisinopril) Tablets.	19–558/S–027
Depakote (divalproex sodium) Sprinkle Capsules.	19–680/S–008
Saizen (somatropin) for Injection.	19–764
Zestril (lisinopril) Tablets.	19–777/S–023
Nasacort (triamcinolone acetonide) Inhalation Aerosol.	19–798/S–006
Prilosec (omeprazole) Capsules.	19–810/S–033 and S–037
Pro-amatine (midodrine hydrochloride) Tablets.	19–815
Renova (tretinoin) Cream.	19–963
Aredia (pamidronate disodium) for Injection.	20–036/S–011
Lioresal (baclofen) Injection.	20–075/S–004
Imitrex (sumatriptan succinate) Injection.	20–080/S–004
Zofran (ondansetron hydrochloride) Tablets.	20–103/S–004
Acthrel (corticorelin ovine triflutate) for Injection.	20–162
Nilandron (nilutamide) Tablets.	20–169
Elmiron (pentosan polysulfate sodium) Capsules.	20–193
Zinecard (dexrazoxane) for Injection.	20–212
Ethyol (amifostine) for Injection.	20–221 and 20–221/S–002
Luvox (fluvoxamine maleate) Tablets.	20–243/S–004

Drug	Application Number
Intralipid (fat emulsion) I.V. Infusion.	20–248
Voltaren XR (diclofenac sodium) Tablets.	20–254
Monpril HCT (fosinopril sodium/ hydrochlorthiazide) Tablets.	20–286
Zyloprim (allopurinol sodium) for Injection.	20–298
Fludeoxyglucose F–18 Injection.	20–306
Oxilan (ioxilan) Injection.	20–316
Zyrtec (cetirizine hydrochloride) Syrup.	20–346
Visipaque (iodixanol) Injection.	20–351
Wellbutrin (bupropion hydrochloride) Tablets.	20–358
Myoview (technetium TC99M tetrofosmin) Injection.	20–372
Cordarone (amiodarone hydrochloride) Injection.	20–377
Nicotrol (nicotine) Nasal Spray.	20–385
Tiazac (diltiazem hydrochloride) Capsules.	20–401
Zerit (stavudine) Oral Solution.	20–413
Remeron (mirtazapine) Tablets.	20–415
Feridex (ferumoxides) Injection.	20–416
Femstat (butoconazole nitrate) Vaginal Cream.	20–421
Azelex (azelaic acid) Cream.	20–428
Vesanoid (tretinoin) Capsules.	20–438
Timolol Ophthalmic Solution.	20–439
Flolan (epoprostenol sodium) for Injection.	20–444
Cerebyx (fosphenytoin sodium) Injection.	20–450
Cytovene (ganciclovir) Capsules.	20–460/S–005
Azulfidine (sulfasalazine) Tablets.	20–465
Nasacort AQ (triamcinolone acetonide) Nasal Spray.	20–468
Claritin-D (loratadine/ pseudoephedrine sulfate) Tablets.	20–470
Tagamet HB (cimetidine hydrochloride) Tablets.	20–473
Ultane (sevoflurane) Inhalation.	20–478
Valtrex (valacyclovir hydrochloride) Caplets.	20–487
Corvert (ibutilide fumarate) Injection.	20–491
Amaryl (glimepiride) Tablets.	20–496
Actron (ketoprofen) Tablets/Caplets.	20–499
Proventil HFA (albuterol sulfate) Inhalation Aerosol.	20–503
Tiamate (diltiazem malate) Tablets.	20–506
Teczem (diltiazem malate/enalapril maleate) Tablets.	20–507
Lac-Hydrin (ammonium lactate) Cream.	20–508
Gemzar (gemcitabine hydrochloride) Injection.	20–509
Zantac (ranitidine hydrochloride) Tablets.	20–520
Mentax (butenafine hydrochloride) Cream.	20–524
Gyne-Lotrimin 3 (clotimazole) Vaginal Inserts.	20–525
Conjugated estrogens/ Medroxyprogesterone acetate Tablets.	20–527
Mavik (trandolapril) Tablets.	20–528
Iontocaine (lidocaine/ epinephrine) Topical Solution.	20–530
Metrocream (metronidazole) Cream.	20–531
Ivy-Block (quaternium-18 bentonite) Lotion.	20–532
Naropin (ropivacaine hydrochloride) Injection.	20–533
Nicotrol (nicotine) Transdermal System.	20–536
Arimidex (anastrozole) Tablets.	20–541
Dopamine hydrochloride in 5% Dextrose Injection.	20–542
Accolate (zafirlukast) Tablets.	20–547
Flovent (fluticasone propionate) Inhalation Aerosol.	20–548
Nimbex (cisatracurium besylate) Injection.	20–551
Oxycontin (oxycodone hydrochloride) Tablets.	20–553
Dovonex (calcipotriene) Cream.	20–554
Axid AR (nizatidine) Tablets.	20–555
Tritec (ranitidine bismuth citrate) Tablets.	20–559
Humalog (insulin lispro) Injection.	20–563
Epivir (lamivudine) Tablets.	20–564
Vitrasert (ganciclovir) Implant.	20–569
Camptosar (irinotecan hydrochloride) Injection.	20–571
Buphenyl (phenylbutyrate sodium) Tablets.	20–572
Buphenyl (phenylbutyrate sodium) Oral Powder.	20–573
Lidocaine Transoral Delivery System.	20–575
Cystadane (betaine) Oral Powder.	20–576
Elliotts B Solution	20–577
Zoladex (goserelin acetate) Implant.	20–578
Lodine (etodolac) Tablets.	20–584
Risperdal (risperidone) Oral Solution.	20–588
Children's Advil (ibuprofen) Oral Suspension.	20–589
Tarka (trandolapril/ verapamil hydrochloride) Tablets.	20–591
Zyprexa (olanzapine) Tablets.	20–592
Epivir (lamivudine) Oral Solution.	20–596
Xalatan (latanoprost) Ophthalmic Solution.	20–597
Rilutek (riluzole) Tablets.	20–599
Jr. Strength Motrin (ibuprofen) Caplets.	20–602
Children's Motrin (ibuprofen) Oral Drops.	20–603
Serostim (somatropin) for Injection.	20–604
Alphagan (brimonidine tartrate) Ophthalmic Solution.	20–613
Clonidine hydrochloride Injection.	20–615
Kadian (morphine sulfate) Capsules.	20–616
Allegra (fexofenadine hydrochloride) Capsules.	20–625
Invirase (saquinavir) Capsules.	20–628
Denavir (penciclovir) Cream.	20–629

Drug	Application Number
Ultiva (remifentanil hydrochloride) Injection.	20–630
Morphine Sulfate Injection.	20–631
Viramune (nevirapine) Tablets.	20–636
Gliadel Wafer (polifeprosan 20 with carmustine) Implant.	20–637
Tavist-D (clemastine fumerate/phenylpropanolamine hydrochloride) Tablets.	20–640
Claritin (loratadine) Syrup.	20–641
Eldepryl (selegiline hydrochloride) Capsules.	20–647
Norvir (ritonavir) Oral Solution.	20–659
Albenza (albendazole) Tablets.	20–666
Hycamtin (topotecan hydrochloride) Injection.	20–671
Norvir (ritonavir) Capsules.	20–680
Crixivan (indinavir sulfate) Capsules.	20–685
Dexferrum (iron dextran) Injection.	40–024
Blenoxane (bleomycin sulfate) for Injection.	50–443/S–025
Maxipime (cefepime hydrochloride) for Injection.	50–679
Daunoxome (liposomal daunorubicin) Injection.	50–704
Merrem (meropenem) Injection.	50–706
Doxil (liposomal doxorubicin) Injection.	50–718
Augmentin (amoxicillin/clavulanic acid) Tablet.	50–720
Biaxin (clarithromycin) Tablets.	50–721
Abelcet (amphotericin B lipid complex) Injection.	50–724/S–002
Augmentin (amoxicillin/clavulanate potassium) Oral Suspension.	50–725
Augmentin (amoxicillin/clavulanate potassium) Tablets.	50–726
Zithromax (azithromycin) Tablets.	50–730

As part of its review of each of the NDA's, ANDA's, and supplements listed in this table, FDA reviewed an EA. In each instance, FDA found that the approval of the NDA, ANDA, 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 § 25.32, FDA prepared a FONSI for each NDA, ANDA, 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. For additional information regarding the submission of freedom of information requests, call 301–443–6310.

Dated: April 21, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–10911 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Geological Survey

Technology Transfer Act of 1986

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of proposed Cooperative Research and Development Agreement (CRADA) negotiations.

SUMMARY: The United States Geological Survey (USGS) is planning to enter into a Cooperative Research and Development Agreement (CRADA) with Now What Software, San Francisco, California. The purpose of the CRADA is to jointly research and develop earth-science related mapping products for commercial distribution. Any other organization interested in pursing the possibility of a CRADA for similar kinds of activities should contact the USGS.

ADDRESSES: Inquiries may be addressed to the Acting Chief of Research, U.S. Geological Survey, National Mapping Division, 500 National Center, 12201 Sunrise Valley Drive, Reston, Virginia 20192; Telephone (703) 648–4643, facsimile (703) 648–4706; Internet ''ebrunson@usgs.gov''.

FOR FURTHER INFORMATION CONTACT: Ernest B. Brunson, address above.

SUPPLEMENTARY INFORMATION: This notice is to meet the USGS requirement stipulated in the Survey Manual.

Dated: April 14, 1997.

Richard E. Witmer,

Acting Chief, National Mapping Division.

[FR Doc. 97–10789 Filed 4–25–97; 8:45 am]

BILLING CODE 4310–31–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[HE–952–9911–01–24 1A; OMB Approval Number 1004–NEW]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The Bureau of Land Management (BLM) has submitted the proposed collection of information listed below to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) On December 19, 1996, BLM published a notice in the **Federal Register** (61 FR 67059) requesting comments on this proposed collection. The comment period ended on February 18, 1996. BLM received no comments from the public in response to that notice. Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the BLM clearance officer at the telephone number listed below.

OMB is required to respond to this request within 60 days but may respond after 30 days. For maximum consideration your comments and suggestions on the requirement should be made within 30 days directly to the Office of Management and Budget, Interior Department Desk Officer (1004–NEW), Office of Information and Regulatory Affairs, Washington, DC 20503, telephone (202) 395–7340. Please provide a copy of your comments to the Bureau Clearance Officer (WO–630), 1849 C St., NW., Mail Stop 401 LS, Washington, DC 20240.

Nature of Comments: We specifically request your comments on the following:

1. Whether the collection of information is necessary for the proper functioning of the Bureau of Land Management, including whether the information will have practical utility;

2. The accuracy of BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;

3. The quality, utility and clarity of the information to be collected; and