will be asked to leave your name, address, and telephone number and will need to refer to Announcement 720. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie M. Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305, telephone: (404) 842–6546, facsimile: (404) 842–6513, E-mail: oxb3@cdc.gov.

Programmatic technical assistance may be obtained from Pat McConnon, M.P.H., National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop C–12, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone: (404) 639–2175, E-mail: pjm2@cdc.gov.

Please refer to Announcement 720 when requesting information regarding this program.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the INTRODUCTION through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325, telephone (202) 512–1800.

Dated: April 22, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–10830 Filed 4–25–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC), announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Savannah River Site Health Effects Subcommittee (SRS).

Times and Dates: 8:30 a.m.–5 p.m., May 15, 1997, 8:30 a.m.–12 noon, May 16, 1997.

Place: Holiday Inn Select, 130 Clairemont Avenue, Decatur, Georgia 30030.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS has delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include: presentations from the National Center for Environmental Health (NCEH) regarding current activities and the National Institute for Occupational Safety and Health and ATSDR will provide updates on the progress of current studies.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Paul G. Renard or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: April 22, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office,Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–10828 Filed 4–25–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0143]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by May 28, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507) FDA has submitted the following proposed collection of information to OMB for review and clearance.

Citizen Petition—21 CFR Part 10.30—(OMB Control Number 0910–0183—Reinstatement)

The Administrative Procedure Act (5 U.S.C. 553(e)) provides that every agency shall accord any interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) provides that any person may submit to the agency a citizen petition requesting the Commissioner of Food and Drugs to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

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