models and any updated scientific data. Additionally, the U.S. Army Center for Health Promotion and Prevention Medicine (USACHPPM) has overseen an initiative to re-evaluate existing AELs for chemical warfare agents and to develop new levels based on currently accepted risk assessment approaches and incorporation of data which has recently become available.

Purpose: The purpose of this meeting is to review the AELs set for GA, GB, and VX based on the 1988 recommendations from CDC and determine modifications required to update these limits to reflect current findings. Based on new risk assessment models and any available scientific data, CDC will engage nerve agent experts and the public in an evaluation of the current limits and recommend updated limits based on the public comments.

To facilitate the public dialogue, CDC will provide a forum for general public interaction and serve as a vehicle for members of the public to provide their individual concerns.

Matters To Be Discussed: Agenda items include (1) presentation of newly developed risk assessment models and scientific data, (2) panel discussion by nerve agent specialists,(3) recommended modifications to existing levels based on panel comments, and (4) collect public comments on proposed new AELs.

There will be time for public input, questions, and comments.

Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Sascha Beck, Chemical Demilitarization Branch, Division of Emergency and Environmental Health Services, NCEH, CDC, 4770 Buford Highway NE (F–16), Atlanta, Georgia, 30341–3724, telephone 770/488–4078, fax 770/488–4127.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for the Centers for Disease Control and Prevention.

Dated: June 15, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–15585 Filed 6–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH).

Time and Date: 9 a.m.–3:30 p.m., July 18, 2000.

Place: The Washington Court, 525 New Jersey Avenue, NW, Washington, DC 20001–1527.

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

Purpose: The BSC, NIOSH is charged with providing advice to the Director, NIOSH on NIOSH research programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings, and disseminating results.

Matters To Be Discussed: Agenda items include a report from the Director of NIOSH; Agriculture Subcommittee Interim Report; Beryllium Research Collaboration; Report on Institute of Medicine Workforce Needs Assessment; NIOSH/NCI Diesel Study: Update and Review of Case-Control Study Questionnaire; Overview of Work Organization Research in NIOSH; and future activities of the Board.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: James W. Stephens, Ph.D., Executive Secretary, BSC, NIOSH, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–3773, fax 404/639–2170, e-mail: jws9@cdc.gov.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 15, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–15583 Filed 6–20–00; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Information Collection Items in the Head Start Performance Standards (current rule).

OMB No.: 0970–0148.

Description: The Head Start Performance Standards are regulations which establish standards for Head Start grantee and delegate agencies to follow to administer quality programs as required by law. Local programs are monitored for compliance with these standards. The information collection aspects of the Performance Standards are one part of the many actions that local agencies must take to ensure they administer quality programs. Almost all these information collection items are record keeping requirements such as recording: nutrition assessment data, family Partnership development, and regular volunteer screening for tuberculosis. These records are intended to act as a management tool for grantees to use in their daily operations. Such records are maintained by the grantees and are not information items which must be collected and then forwarded to he Federal government.

Respondents: Head Start grantee and delegate agencies

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Performance Standards	2,472	1	594	1,468,626
Estimated Total Annual Burden Hours.				1,468,626

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the *Federal Register.* Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written

comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: June 15, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–15547 Filed 6–20–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0842]

Determination That Ranitidine Effervescent 75–Milligram Tablet Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that ranitidine effervescent 75-milligram (mg) tablet (Zantac Efferdose) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for ranitidine effervescent 75-mg tablet.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Ranitidine effervescent 75-mg tablet is the subject of NDA 20–745. FDA approved NDA 20–745, held by Glaxo Wellcome, Inc. (Glaxo), on February 26, 1998. Glaxo never marketed the ranitidine effervescent 75-mg tablet. Glaxo transferred ownership of NDA 20–745 to the Warner-Lambert Co. (Warner-Lambert) effective January 1, 1999. To date, Warner-Lambert has not marketed the ranitidine effervescent 75-mg tablet.

On March 1, 2000, Thomas Blake, R.Ph., submitted a citizen petition (Docket No. 00P–0842/CP1) under 21 CFR 10.30 to FDA. The petition requested that the agency determine whether ranitidine effervescent 75-mg tablet was withdrawn from sale for reasons of safety or effectiveness. FDA has determined that, for the purposes of § 314.161, never marketing an approved drug product is equivalent to withdrawing the drug product from sale.

FDA has reviewed its records and, under § 314.161, has determined that the decision by Glaxo and Warner-Lambert not to market ranitidine effervescent 75-mg tablet was not for reasons of safety or effectiveness. Accordingly, the agency will maintain ranitidine effervescent 75-mg tablet in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to ranitidine effervescent 75-mg tablet may be approved by the agency.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–15555 Filed 6–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0585]

Determination That Fluoxetine Hydrochloride 20–Milligram Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that fluoxetine hydrochloride 20-milligram (mg) tablets (Prozac®) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for fluoxetine hydrochloride 20-mg tablets.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With