continuous periods include months in more than one taxable year pursuant to the last paragraph of 26 U.S.C. 5000A(e)(4).

This delegation of authorities supersedes the authorities delegated under Title XXVII of the Public Health Service Act that were published in the **Federal Register** notice on June 23, 1998 (63 FR 34190).

This delegation of authorities is effective immediately.

These authorities may be re-delegated.

These authorities shall be exercised under the Department's policy on regulations and the existing delegation of authority to approve and issue regulations.

I hereby affirm and ratify any actions taken by the Administrator, CMS, or his or her subordinates, which involved the exercise of the authorities under Titles I, II, and X of the Affordable Care Act, including Title XXVII of the Public Health Service Act delegated herein prior to the effective date of this delegation of authorities.

Authority: 44 U.S.C. 3101.

Dated: August 2, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–22042 Filed 8–29–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–270]

Availability of Final Toxicological Profile for RDX

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of one toxicological profile, prepared by ATSDR for the Department of Defense, on Royal Demolition eXplosive (RDX), chemical name hexahydro-1,3,5-trinitro-1,3,5-triazine, also known as cyclonite.

FOR FURTHER INFORMATION CONTACT: Ms. Delores Grant, Division of Toxicology and Environmental Medicine, Agency for Toxic Substances and Disease Registry, Mailstop F–62, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (770) 488–3351.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act (SARA) of 1986 (Pub. L. 99–499) amended the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund). Section 211 of SARA also amended Title 10 of the U.S. Code, creating the Defense Environmental Restoration Program. Section 2704 of Title 10 of the U.S. Code directs the Secretary of Defense to notify the Secretary of Health and Human Services (HHS) of not less than 25 of the most commonly found unregulated hazardous substances at defense facilities. The Secretary of HHS is to prepare toxicological profiles of these substances. Each profile is to include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information is used to ascertain the level of significant human exposure for the substance and the associated health effects. The toxicological profile includes a determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), may plan a program of research designed to determine these health effects.

Notice of the availability of the draft profile for public review and comment was published in the **Federal Register** on August 26, 2010, (75 FR 52535), with notice of a 90-day public comment period starting from the actual release date. Following the close of the comment period, chemical-specific comments were addressed, and, where appropriate, changes were incorporated into each profile. The public comments and other data submitted in response to the **Federal Register** notice bears the docket control number ATSDR–266. This material is available for public inspection at the Agency for Toxic Substances and Disease Registry, 4700 Buford Highway, Building 106, Second Floor, Chamblee, Georgia 30341 between 8 a.m. and 4:30 p.m., Monday through Friday, except legal holidays.

Availability

This notice announces the availability of one updated final toxicological profile, RDX, prepared by ATSDR for the Department of Defense. Electronic access to this document is available at the ATSDR Web site: *http://www.atsdr.cdc.gov/toxprofiles/index.asp.*

A printed copy of this toxicological profile is available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, telephone 1–800–553–6847. There is a charge for this profile as determined by NTIS.

Hazardous substance	NTIS Order No.	CAS Number
RDX	PB2011–xxx	121–82–4

Dated: August 24, 2011.

Ken Rose,

Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. 2011–22080 Filed 8–29–11; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: ORR State Plan for Grants to States for Refugee Resettlement.

OMB No. 0970–0351.

Description: A State Plan is required by 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [Title IV, Sec. 412 of the Act] for each State agency requesting Federal funding for refugee resettlement under 8 U.S.C. 524 [Title IV, Sec. 414 of the Act], including Refugee Cash and Medical Assistance, Refugee Social Services, and Targeted Assistance program funding. The State Plan is a comprehensive narrative description of the nature and scope of a States programs and provides assurances that the programs will be administered in conformity with the specific requirements stipulated in 45 CFR 400.4–400.9. The State Plan must

include all applicable State procedures, designations, and certifications for each requirement as well as supporting documentation. A State may use a pre-print format prepared by the Office of Refugee Resettlement (ORR) of the Administration for Children and Families (ACF) or a different format, on the condition that the format used meets all of the State plan requirements under Title IV of the Act and ORR regulations at 45 CFR part 400.

There is no schedule for submission of this State Plan, as all States are currently operating under an approved plan and are in compliance with regulations at 45 CFR 400.4 400.9. Per 45 CFR 400.4(b), States need only certify that the approved plan is current and continues in effect, no later than 30 days after the beginning of the Federal fiscal year. Consistent with regulations, if States wish to revise or amend the plan, a revised plan or plan amendment must be submitted to ORR as described at 45 CFR 400.7 400.9.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV State Plan	50	1	15	750

Estimated Total Annual Burden Hours: 750.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–22078 Filed 8–29–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0460]

Determination That TALWIN COMPOUND (Aspirin; Pentazocine Hydrochloride) Tablets, 325 Milligrams; Equivalent to 12.5 Milligram Base, 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) has determined that TALWIN COMPOUND (aspirin; pentazocine hydrochloride (HCl)) tablets, 325 milligrams (mg); equivalent to (EQ) 12.5 mg base, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for aspirin; pentazocine HCl tablets, 325 mg; EQ 12.5 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, are the subject of NDA 016891, held by Sanofi-aventis U.S., and initially approved on November 12, 1975. TALWIN COMPOUND tablets are indicated for the relief of moderate pain.

TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, are currently listed in the