ANNUAL BURDEN ESTIMATES

[Data collection will be completed within a one-year period]

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Coach Survey (Instrument 1)	100	1	.33	33
Center Director Survey (Instrument 2)	66	1	.33	22
FCC Provider Survey (Instrument 3)	38	1	.33	13
Coach Interview (Instrument 4)	12	1	.75	9
Center Director Interview (Instrument 5)	24	1	.75	18
FCC Provider Interview (Instrument 6): FCC providers	12	1	.75	9

Estimated Total Annual Burden Hours: 104.

Authority: 42 U.S.C. 9858(a)(5), 42 U.S.C. 9835, and 42 U.S.C. 9844.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–08614 Filed 4–23–21; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–2304]

Determination That Sodium Chloride 14.6% Solution for Injection, 50 Milliequivalent/20 Milliliters, in Plastic Containers, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 or Agency) has determined that Sodium Chloride 14.6% solution for injection, 50 milliequivalent (mEq)/20 milliliters (mL), in plastic containers, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–4191, *Ayako.Sato@fda.hhs.gov.*

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 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.

Sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, is the subject of NDA 18897, held by Hospira Inc., and initially approved on July 20, 1984. Sodium chloride 14.6% solution for injection is indicated for use as an electrolyte replenisher in parenteral fluid therapy.

In a communication dated September 6, 2019, Hospira Inc. notified FDA that sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Fresenius Kabi USA, LLC submitted a citizen petition dated December 16, 2020 (Docket No. FDA–2020–P–2304), under 21 CFR 10.30, requesting that the Agency determine whether sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, 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. ANDAs that refer to sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08615 Filed 4–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: 0937–0191–30D]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 26, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: 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; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Collection: Reinstatement w/ without chg.

OMB No.: 0937–0191.

Abstract: The Office of Assistant Secretary for Administration, Program Support Center, Federal Real Property Assistance Program is requesting OMB approval on a previously approved information collection, 0937–0191. 40 U.S.C. 550 (the ''Act''), as amended, provides authority to the Secretary of Health and Human Services to convey or lease surplus real property to States and their political subdivisions and instrumentalities, to tax-supported institutions, and to nonprofit institutions which (except for institutions which lease property to assist the homeless) have been held exempt from taxation under Section 501(c)(3) of the 1954 Internal Revenue Code, and 501(c)(19) for veterans organizations, for public health and homeless assistance purposes. Transfers are made to transferees at little or no cost.

Type of respondent: Responses are dependent on when Federal surplus real property is made available and is desired by a respondent/applicant for acquisition. Likely respondents include State, local, or tribal units of government or instrumentalities thereof, and not-for-profit organizations.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Applications for surplus Federal real property		15	1	200	3,000
Total		15	1	200	3,000

Dated: January 19, 2021.

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

Editorial note: This document was received for publication by the Office of the Federal Register on April 20, 2021.

[FR Doc. 2021–08548 Filed 4–23–21; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Muscular Dystrophy Coordinating Committee (MDCC).

The meeting will be open to the public. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: June 2, 2021.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: The purpose of this meeting is to bring together committee members, representing government agencies, patient advocacy groups, other voluntary health organizations, and patients and their families to update one another on progress relevant to the Action Plan for the Muscular Dystrophies and to coordinate activities and discuss gaps and opportunities leading to better understanding of the muscular dystrophies, advances in treatments, and improvements in patients' and their families' lives. The agenda for this meeting is available on the MDCC website: *https://www.mdcc.nih.gov/Meetings_Events/june-2-2021.*

Registration: To register, please go to: *https://roseliassociates.zoomgov.com/webinar/register/WN_ihQyf5oBTNK706B9fAHpfQ.*

Webcast Live: https://videocast.nih.gov/watch=41965.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Glen Nuckolls, Ph.D., Program Director, National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Blvd., Rm 2203, Bethesda, MD 20892, 301–496–5876, *MDCC@nih.gov.*