Estimated Total Annual Burden Hours: 3,883.

Authority: 42 U.S.C. 652(a)(7); 42 U.S.C. 666(c)(1); and 45 CFR 303.7(a)(5).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–08770 Filed 4–22–22; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comprehensive Child Welfare Information System (CCWIS) Automated Function Checklist and Data Quality Plan (OMB #0970–0463)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Comprehensive Child Welfare Information System (CCWIS) information collection (OMB #0970–0463, expiration 8/31/2022). The CCWIS information collection includes the Automated Function List and the Data Quality Plan. There are no required instruments associated with the data collection and no changes to the data collection.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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.

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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The CCWIS information collection includes two components:

- The Automated Function List update required pursuant to section 1355.52(i)(2); and
- The Data Quality Plan update required pursuant to section 1355.52(d)(5).

The CCWIS regulations require updates of this information to confirm that the project meets CCWIS requirements and that project costs are appropriately allocated to benefiting programs.

Respondents: Title IV–E agencies under the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Automated Function List section 1355.52(i)(2)	55	1	10	550
Data Quality Plan section 1355.52(d)(5)	55	1	40	2,200

Estimated Annual Burden Hours: 2,750.

Authority: 42 U.S.C. 620 *et seq.,* 42 U.S.C. 670 *et seq.,* 42 U.S.C. 1301 and 1302.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–08732 Filed 4–22–22; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4206]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by May 25, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. All comments should be identified with the OMB control number 0910–0508. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

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

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910–0508—Extension

This information collection helps support implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250) and FDA's Medical Device User Fee program. Current authorization for medical device user fees will be in place from October 1, 2017, until September 30, 2022.

Section 738(d)(2)(A) and (e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A)) define a ''small business'' as an entity that reported $100 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms. If a firm's gross receipts or sales are no more than

$30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application, product development protocol, biological licensing application, or premarket report. A ''small business'' is eligible for reduced or waived fees. If an applicant does not provide information to FDA demonstrating to FDA's satisfaction that the applicant is a small business, the applicant must pay the standard (full) fee for any application it submits.

Forms FDA 3602 (''MDUFA Small Business Certification Request for a Business Headquartered in the United States'') and 3602A (''MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States'') are submitted to FDA to demonstrate that an applicant qualifies as a MDUFA small business. The guidance ''Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' [1] describes the process by which a business may request certification as a small business and the criteria FDA will use to decide whether an entity qualifies as a MDUFA small business and is eligible for a reduction in user fees.

In the **Federal Register** of December 23, 2021 (86 FR 72983), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, however it did not respond to the functional elements solicited in our 60-day notice or suggest a revision to our burden estimate.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3602—MDUFA Small Business Certification Request For a Business Headquartered in the United States	2,500	1	2,500	1	2,500
FDA 3602A—MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000
Total					4,500

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

Our estimated burden is based on the number of applications received in the last few years and includes the time we assume necessary to prepare and submit required information. Based on our experience with Forms FDA 3602 and 3602A, we assume it will take respondents 1 hour to complete either form. We have adjusted our estimated ''No. of Respondents'' to better reflect recent submission volume. This adjustment results in a 2,500-hour decrease to the information collection.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08726 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1975–N–0336 (formerly 1975N–0184)]

Drugs for Human Use; Drug Efficacy Study Implementation; Oral Prescription Drugs Containing an Anticholinergic or Antispasmodic in Combination With a Sedative, and Single-Entity Antispasmodic Drug Products, in Oral Dosage Form; Withdrawal of Hearing Requests; Final Resolution of Drug Efficacy Study Implementation

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that all outstanding hearing requests regarding drug products containing an anticholinergic or antispasmodic in combination with a sedative, and single-entity antispasmodic drug products, in oral dosage form, under Docket FDA–1975–N–0336 (formerly 75N–0184) (DESI 10837) have been withdrawn. Therefore, shipment in interstate commerce of any such product identified in Docket FDA–1975–N–0336 covered by DESI 10837, or any identical, related, or similar (IRS) product, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) is unlawful as of the date of this notice. This notice does not affect products covered by DESI 597 under the same docket.

DATES: This notice is applicable April 25, 2022.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The most relevant background documents regarding this matter are available in the docket. However, additional background documents are available upon request (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Jeffrey Trunzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5111,

[1] The guidance ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification.*