

Estimated Total Annual Burden Hours: 3,090.53.

Authority: 42 U.S.C. 652(a)(9), 42 U.S.C. 653(a)(1) and 42 U.S.C. 652(m).

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2023–24857 Filed 11–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Multistate Financial Institution Data Match With Federally Assisted State Transmitted Levy (OMB No.: 0970–0169)

AGENCY: Office of Child Support Services Office, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Services (OCSE), Administration for Children and Families (ACF), is requesting the federal Office of

Management and Budget (OMB) to extend approval of the Multistate Financial Institution (MSFIDM) Data Match with Federally Assisted State Transmitted (FAST) Levy, without changes, for an additional three years. The current OMB approval expires January 31, 2024.

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: State child support agencies are statutorily required to enter into data matching agreements with financial institutions doing business in their state to locate obligors’ accounts. OCSE operates the MSFIDM program through the Federal Parent Locator Service (FPLS) and facilitates the required data match between state child support agencies and multistate financial institutions (MSFIs). State child support agencies use the data match outcomes to fulfill a statutory requirement to seize an obligor’s assets to satisfy past due child support payments.

OCSE also operates FAST Levy, which is an automated application within the FPLS to exchange electronic lien/levy information securely and efficiently. State child support agencies and MSFIs use FAST Levy to seize financial assets more quickly and efficiently.

Respondents: Multistate Financial Institutions and State Child Support Agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total annual number of respondents	Total annual number of responses per respondent	Average annual burden hours per response	Total annual burden hours
Financial Data Match Record Specifications Match File Upload/Download: Portal Users	263	4	0.083	87.3
Election Form	13	1	0.5	6.5
FAST-Levy Response Withhold Record Specifications: Financial Institutions	1	1	1,716	1,716.0
FAST-Levy Request Withhold Record Specifications: State Child Support Agencies	2	1	1,610	3,220.0

Estimated Total Annual Burden Hours: 5,029.8.

Authority: 42 U.S.C. 652(l); 42 U.S.C. 666(a)(2) and (c)(1)(G)(ii); 42 U.S.C. 666(a)(17)(A); 42 U.S.C. 652(a)(7); and, 45 CFR 303.7(a)(5).

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2023–24855 Filed 11–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4720]

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Multi-Cancer Detection Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Molecular and Clinical Genetics Panel of the Medical Devices

Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will take place virtually on November 29, 2023, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2023-N-4720. Please note that late, untimely filed comments will not be considered. The docket will close on December 29, 2023. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 29, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before November 15, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-4720 for "Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: 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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993-0002, Candace.Nalls@fda.hhs.gov, 301-636-0510, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On November 29, 2023, the committee will discuss and make recommendations on the design of multi-cancer detection (MCD) in vitro diagnostic devices (tests) as well as potential study designs and study outcomes of interest that could inform the assessment of the probable benefits and risks of MCD screening tests. The committee's discussion and recommendations from this meeting will help inform future Agency regulatory efforts for these novel tests.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down and select the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and

written submissions may be made to the contact person on or before November 15, 2023 will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:45 a.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 16, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 17, 2023.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at Artair.Mallett@fda.hhs.gov or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: November 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-24896 Filed 11-9-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-P-2055]

Determination That COGENTIN (Benztropine Mesylate) Injection, 1 Milligram per 1 Milliliter, 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 the Agency) has determined that COGENTIN (benztropine mesylate) Injection, 1 milligram (mg)/1 milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993-0002, 301-796-4455, Nisha.Shah@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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 FDA's approval of 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.

COGENTIN (benztropine mesylate) Injection, 1 mg/1 mL, is the subject of NDA 012015, held by Akorn Operating Company LLC, and initially approved on December 21, 1959. COGENTIN is indicated for use as an adjunct in the therapy of all forms of parkinsonism and for the control of extrapyramidal disorders (except tardive dyskinesia) due to neuroleptic drugs (*e.g.*, phenothiazines).

In a letter dated March 18, 2022, Akorn Operating Company LLC notified FDA that COGENTIN (benztropine mesylate) Injection, 1 mg/1 mL, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Nexus Pharmaceuticals submitted a citizen petition dated May 19, 2023 (Docket No. FDA-2023-P-2055), under 21 CFR 10.30, requesting that the Agency determine whether COGENTIN (benztropine mesylate) Injection, 1 mg/1 mL, 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 COGENTIN (benztropine mesylate) Injection, 1 mg/1 mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of COGENTIN (benztropine mesylate) Injection, 1 mg/1 mL, from sale. We have also independently evaluated