

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Digestive Sciences Small Business Activities.

*Date:* March 18, 2021.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435-5947, [banerjees5@mail.nih.gov](mailto:banerjees5@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular and Surgical Devices.

*Date:* March 18–19, 2021.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review National Institutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301.402.9607, [Jan.Li@nih.gov](mailto:Jan.Li@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business (HD21–020): Non-invasive Diagnostics to Improve Gynecologic Health.

*Date:* March 18, 2021.

*Time:* 10:00 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Yunshang Piao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6184, Bethesda, MD 20892, 301.402.8402 [piaoy3@mail.nih.gov](mailto:piaoy3@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA Panel: NIH Director's Early Independence Award Review.

*Date:* March 18–19, 2021.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435-1712 [ryansj@csr.nih.gov](mailto:ryansj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Skeletal Muscle Physiology and Rehabilitation.

*Date:* March 18, 2021.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Srikanth Ranganathan, Ph.D., Scientific Review Officer, Center for Scientific Review National Institutes of Health, 6701 Rockledge Drive., Room 4214, MSC 7802, Bethesda, MD 20892, (301) 435-1787, [srikanth.ranganathan@nih.gov](mailto:srikanth.ranganathan@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel—Fertility Status as a Marker for Overall Health.

*Date:* March 18, 2021.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Hui Chen, MD, Scientific Review Officer, Center for Scientific Review National Institutes of Health, 6701 Rockledge Drive, Room 6164, Bethesda, MD 20892, 301-435-1044, [chenhui@csr.nih.gov](mailto:chenhui@csr.nih.gov).

*Name of Committee:* Center for Scientific Review, Special Emphasis Panel; Small Business: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

*Date:* March 18–19, 2021.

*Time:* 12:30 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Yunshang Piao, Ph.D., Scientific Review Officer, Center for Scientific Review National Institute of Health, 6701 Rockledge Drive, Room 6184, Bethesda, MD 20892, 301.402.8402, [piaoy3@mail.nih.gov](mailto:piaoy3@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 11, 2021.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021–03189 Filed 2–17–21; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–D–0575]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expedited Programs for Serious Conditions—Drugs and Biologics

**AGENCY:** Food and Drug Administration, 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:** Submit written comments (including recommendations) on the collection of information by March 22, 2021.

**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. The OMB control number for this information collection is 0910–0765. 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–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### Expedited Programs for Serious Conditions—Drugs and Biologics

*OMB Control Number 0910–0765—Extension*

This information collection supports Agency regulations and associated guidance pertaining to expedited programs for serious conditions. The purpose of our regulations in 21 CFR part 312, subpart E is to establish procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely debilitating illnesses, especially where no satisfactory alternative therapy exists. While the statutory standards of safety and effectiveness apply to all drugs, the many kinds of drugs that are subject to them, and the wide range of uses for those drugs, demand flexibility in applying the standards.

We have developed the guidance for industry entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” as a single resource for information on FDA’s policies and procedures related to the following

expedited programs for serious conditions: (1) Fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. The guidance describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. The guidance addresses the applicability of expedited programs to rare diseases, clarification on available therapy, and additional detail on possible flexibility in manufacturing and product quality. It also clarifies the qualifying criteria for breakthrough therapy designation and provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval.

A sponsor or applicant who seeks fast track designation is required to submit to us a request showing that the drug product: (1) Is intended for a serious or life-threatening condition and (2) has the potential to address an unmet medical need. We expect that most information to support a designation request will have been gathered under existing requirements for preparing an investigational new drug application (IND), new drug application (NDA), or biologics license application (BLA). If such information has already been submitted to us, the information may be summarized in the fast track designation request. A designation request should include, where applicable, additional information not specified elsewhere by

statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After we make a fast track designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, we expect that most sponsors or applicants will have gathered such information to meet existing requirements for preparing an IND, an NDA, or a BLA. These may include descriptions of clinical safety and efficacy trials not conducted under an IND (e.g., foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to us, the information may be summarized in the premeeting package.

We also developed the guidance document entitled “Expedited Programs

for Regenerative Medicine Therapies for Serious Conditions.” The guidance provides sponsors engaged in the development of regenerative medicine therapies for serious or life-threatening diseases or conditions with FDA’s recommendations on the expedited development and review of these therapies. The guidance describes the expedited programs available to sponsors of regenerative medicine therapies for serious or life-threatening diseases or conditions, including those products designated as regenerative advanced therapies (which FDA refers to as “regenerative medicine advanced therapy” (RMAT) designation). The guidance also describes considerations in the clinical development of regenerative medicine therapies and opportunities for sponsors of regenerative medicine therapies to interact with the Center of Biologics Evaluation and Research review staff.

The guidance documents are available on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> and were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

In the **Federal Register** of November 18, 2020 (85 FR 73487), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Designation Requests .....	70	1.44	101	30	3,030
Breakthrough Therapy Designation Requests .....	119	1.31	156	70	10,920
Fast Track Designation Requests .....	205	1.273	261	60	15,660
RMAT Designation Requests .....	33	1.15	38	60	2,280
Fast Track Premeeting Packages .....	224	1.75	392	100	39,200
Total .....	.....	.....	948	.....	71,090

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimates by 389 responses and 35,325 hours. As reflected in table 1, we estimate that 70 respondents will submit 101 requests for priority review designation annually. We assume an average of 30 hours is needed to prepare such a request.

We estimate that 119 respondents will submit 156 requests for breakthrough

designation annually and assume that an average of 70 hours is needed to prepare such a request.

We estimate 205 respondents will submit 261 requests for fast track designation requests annually and assume that an average of 60 hours is needed to prepare such a request.

Of the requests for fast track designation made per year, we granted approximately 224 requests from 392 respondents, and for each of these

granted requests, a premeeting package was submitted. We therefore assume an average burden of 100 hours per respondent for preparing a premeeting package.

Finally, we estimate 33 respondents will submit 38 requests for RMAT designation and assume that an average of 60 hours is needed to prepare such a request.

Dated: February 10, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-03244 Filed 2-17-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0165]

#### International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Isotonitazene; MDMB-4en-PINACA; CUMYL-PEGACLONE; Flubromazolam; Clonazolam; Diclazepam; 3-Methoxyphencyclidine; Diphenidine; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice will be considered in preparing the United States' position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, in April 2021. This notice is issued under the Controlled Substances Act (CSA).

**DATES:** Submit either electronic or written comments by March 22, 2021.

**ADDRESSES:** 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-2021-N-0165 for "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Isotonitazene; MDMB-4en-PINACA; CUMYL-PEGACLONE; Flubromazolam; Clonazolam; Diclazepam; 3-Methoxyphencyclidine; Diphenidine; Request for Comments." Received comments 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." The Agency 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 to 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 this 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:**

James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993-0002, 301-796-3156, [james.hunter@fda.hhs.gov](mailto:james.hunter@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The United States is a party to the 1971 Convention on Psychotropic Substances (1971 Convention). Section 201(d)(2)(B) of the CSA (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the 1971 Convention that the CND proposes to decide whether to add a drug or other substance to one of the schedules of the 1971 Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.