

TABLE 1—GUIDANCES RELATED TO THE COVID-19 PUBLIC HEALTH EMERGENCY—Continued

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA-2020-D-1138	CDRH	Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (October 2020).	<i>CDRH—Guidance@fda.hhs.gov/</i> . Please include the document number 20046 and complete title of the guidance in the request.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not establish any rights for any person and are not binding on

FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

A. CBER Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 2).

Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

TABLE 2—CBER GUIDANCE AND COLLECTIONS

COVID-19 guidance title	CFR cite referenced in COVID-19 guidance	Another guidance title referenced in COVID-19 guidance	OMB control No(s).
Emergency Use Authorization for Vaccines to Prevent COVID-19 (October 2020).	21 CFR 314.420	0910-0001
	21 CFR part 312	0910-0014
	21 CFR parts 210, 211, and 610	0910-0139
	21 CFR part 600	0910-0308
	21 CFR part 601	0910-0338
	Emergency Use Authorization of Medical Products and Related Authorities.	0910-0595

B. CDRH Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of

information (listed in table 3). Therefore, clearance by OMB under the PRA is not required for this guidance. The previously approved collections of information are subject to review by

OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the table below.

TABLE 3—CDRH GUIDANCE AND COLLECTIONS

COVID-19 guidance title	CFR cite referenced in COVID-19 guidance	Another guidance title referenced in COVID-19 guidance	OMB control No(s).
Enforcement Policy for Modifications to FDA—Cleared Molecular Influenza and RSV Tests During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (October 2020).	800, 801, and 809	N/A	0910-0485
	807, subpart E	0910-0120
	820	0910-0073

IV. Electronic Access

Persons with access to the internet may obtain COVID-19-related guidances at:

- FDA web page entitled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>;

- FDA web page entitled “Search for FDA Guidance Documents” available at

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>; or

- <https://www.regulations.gov>.

Dated: November 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-25399 Filed 11-17-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0575]

Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection pertaining to “Expedited Programs for Serious Conditions—Drugs and Biologics.”

DATES: Submit either electronic or written comments on the collection of information by January 19, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 19, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 19, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2013–D–0575 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics.” 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.” 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://](https://www.regulations.gov)

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:

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.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 (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 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

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 Premeeeting Packages	224	1.75	392	100	39,200
Total			948		71,090

¹ 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 RMA designation and assume that an average of 60 hours is needed to prepare such a request.

Dated: November 12, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-25414 Filed 11-17-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Tuesday, December 1, 2020. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Tuesday, December 1, 2020, from 10:00 a.m. to 2:45 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please register online at <https://www.cvent.com/d/17qsnx> by the deadline of 12:00 p.m. ET on Monday, November 30, 2020. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT:

Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301-443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

- (1) Presentations on the decision making criteria and matrix used to evaluate conditions nominated to the RUSP;
- (2) review of newborn screening implementation for the following RUSP conditions: Severe combined immunodeficiency (SCID), critical congenital heart disease (CCHD), Pompe disease, mucopolysaccharidosis type I (MPS I), X-linked adrenoleukodystrophy (XALD); and
- (3) overview of the Review of Newborn Screening for Spinal Muscular Atrophy (SMA) report and vote on whether to submit this review to the Secretary.

In July 2018, SMA was added to the RUSP, and the Secretary requested a follow-up report that assesses the

impact of implementing screening for SMA. Following the overview of the Review of Newborn Screening for Spinal Muscular Atrophy report, the Committee is expected to vote on whether to submit this review to the Secretary or whether further action is warranted prior to its submission.

The agenda for this meeting does not include any plans for recommending a condition for inclusion in the RUSP. Agenda items are subject to changes as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, are also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by Friday, November 27, 2020, by 10:00 a.m. ET.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

This meeting is being announced less than 15 days prior to the scheduled meeting due to an administrative issue that has now been resolved.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020-25461 Filed 11-17-20; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Treatment and Prevention of Neuropathic Pain With P2Y14 Antagonists

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Saint Louis University, ("SLU"), a non-profit university located in Missouri, in its rights to the inventions and patents listed in the