TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR or FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Subpart E—Postapproval Requirements:					
Postapproval requirements (814.82(a)(9))	121	1	121	135	16,335
Periodic reports (814.84(b))	764	1	764	10	7,640
Total Subpart E					24,005
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance "Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"					
Certification to accompany PMA submissions (Form FDA 3674)	40	1	40	0.75 (45 minutes)	30
FD&C Act section 515A Pediatric Uses of Devices:					
Pediatric information in a PMA, PDP, or PMA supplement	944	1	944	2.10	1984
Pediatric use information outside approved indication	800	1	800	0.5 (30 minutes)	400
Subtotal	1,744	1	1,744		2,384
Premarket Approval Submissions (eSTAR preparation; eCopy submission):					
eSTAR setup	30	1	30	0.08 (5 minutes)	2
Total					343,496

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

Our estimate is based on the annual rate of receipt of PMA submissions, including PDPs and PMA supplements, for fiscal years 2019 through 2021 and our expectation of submissions to come in the next few years. We also account for referrals of PMAs to a panel for review, as provided for under § 814.44(a). FDA may refer the PMA to a panel on its own initiative, and will do so upon request of an applicant, unless FDA determines that the application substantially duplicates information previously reviewed by a panel. We have adjusted our figures to reflect an overall decrease, which we attribute to respondents' use of modernized submission technologies including eSTAR. At the same time, we include in our estimate an initial burden attributable to respondents who need to set up an eSTAR account for the first time.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of records (814.82(a)(5) and (a)(6))	552	1	552	17	9,384

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

The regulations require the maintenance of records, which are used to trace patients, and the organization and indexing of records into identifiable files to ensure a device's continued safety and effectiveness. These records are required of all applicants who have an approved PMA. Currently there are 815 active PMAs that could be subject to these requirements, based on FDA data, and approximately 33 new PMAs are approved each year. We estimate our annual recordkeeping burden based on an average of 552 PMA holders. The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required under 21 CFR part 820 may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

Cumulatively, our adjustments reflect only a slight increase to the estimated burden for the information collection.

Dated: January 25, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2658]

Acromegaly: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Acromegaly: Developing Drugs for Treatment.'' The purpose of this guidance is to provide recommendations to sponsors regarding clinical development of drugs for the treatment of patients with acromegaly. This draft guidance is intended to serve as a focus for continued discussions among the FDA Division of General Endocrinology, pharmaceutical sponsors, the academic community, and the public.

DATES: Submit either electronic or written comments on the draft guidance by March 31, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2022–D–2658 for ''Acromegaly: Developing Drugs for Treatment.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Naomi Lowy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0692.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acromegaly: Developing Drugs for Treatment.'' The purpose of this guidance is to provide recommendations to sponsors regarding clinical development of drugs for the treatment of patients with acromegaly. This draft guidance is intended to serve as a focus for continued discussions among the FDA Division of General Endocrinology, pharmaceutical sponsors, the academic community, and the public.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Acromegaly: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. 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 related to the submission of new drug applications and abbreviated new drug applications under 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information related to the submission of investigational new drug applications under 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information related to the submission of biologics license applications under 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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