ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFCARS	72	2	1,786	257,184

Estimated Total Annual Burden Hours: 257,184.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–26825 Filed 12–12–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0177]

Proposed Information Collection Activity; Comment Request

Title: OCSE–157 Child Support Enforcement Program Annual Data Report.

Description: The information obtained from this form will be used to: (1) Report Child Support Enforcement activities to the Congress as required by law; (2) calculate incentive measures performance and performance indicators utilized in the program; and (3) assist the Office of Child Support Enforcement (OCSE) in monitoring and evaluating State Child Support programs.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–157	54	1	7	378

Estimated Total Annual Burden Hours: 378.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–26814 Filed 12–12–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6554]

Refuse To File: New Drug Application and Biologics License Application Submissions to the Center for Drug Evaluation and Research; 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 ''Refuse to File: NDA and BLA Submissions to CDER.'' The purpose of this guidance is to clarify certain circumstances under which FDA's Center for Drug Evaluation and Research (CDER) may refuse to file a new drug application (NDA) or

supplemental NDA, or a biologics license application (BLA) or supplemental BLA submitted to CDER, and to underscore the importance of submitting a complete application to minimize the chance of a refuse-to-file (RTF) action by FDA.

DATES: Submit either electronic or written comments on the draft guidance by February 12, 2018 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–2017–D–6554 for ''Refuse to File: New Drug Application and Biologics License Application Submissions to the Center for Drug Evaluation and Research; Draft Guidance for Industry.'' 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.

- 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.gpo.gov/fdsys/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.

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: Amalia Himaya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6439, Silver Spring, MD 20993–0002, 301–796–0700.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Refuse to File: NDA and BLA Submissions to CDER.'' The purpose of this guidance is to clarify certain circumstances under which CDER may refuse to file an NDA or supplemental NDA, or a BLA or supplemental BLA submitted to CDER, and to underscore the importance of submitting a complete application to minimize the chance of an RTF action by FDA. Since the early 1990s, in conjunction with the Prescription Drug User Fee Act, FDA's processes and timelines for reviewing newly submitted applications have substantially evolved. The administrative complexity of applications, with corresponding determinations of *completeness,* has become more challenging. The overall goal is to efficiently and effectively review applications, and thus it is critical to avoid use of resources to review an application when necessary components are so deficient as to render the application incomplete. FDA exercises its RTF authority for incomplete applications to optimize the use of both the applicant's and FDA's resources.

Incomplete applications, including applications for which minor components not received within 30 calendar days after receipt of the original application, as may have been agreed upon at a presubmission meeting, may be refused for filing.

This guidance focuses on FDA's policy for refusing to file an NDA under 21 CFR 314.101(d)(3) because the NDA is incomplete because it does not on its face contain information required under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and 21 CFR 314.50. FDA considers incompleteness to be a basis for refusal to file for BLAs as well (21 CFR 601.2(a)).

On May 19, 2017, FDA withdrew its previously published guidance for industry entitled ''Refusal to File'' (issued July 12, 1993). FDA is issuing this guidance to update and clarify CDER's procedures for determining whether an application should be

refused for filing because it is incomplete. This guidance includes procedures for certain BLAs and supplemental BLAs, given that CDER has regulatory responsibility for certain therapeutic biological products subject to licensing under the Public Health Service Act.

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 refusal to file NDA and BLA submissions to CDER. 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. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 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 either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26791 Filed 12–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5925]

21st Century Cures Act: Announcing the Establishment of the Susceptibility Test Interpretive Criteria Website

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of the Susceptibility Test Interpretive Criteria Website. The Susceptibility Test Interpretive Criteria Website will help to efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health and may allow for more efficient development and evaluation of antimicrobial susceptibility test (AST) devices. These changes may lead to better patient care and reduce antimicrobial resistance through improved antibiotic stewardship. FDA is publishing this notice in accordance with procedures established by the 21st Century Cures Act (Cures Act).

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1182, *Katherine.Schumann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial susceptibility testing is used to determine if certain microorganisms that are isolated from a patient with an infection are likely to be killed or inhibited by a particular antimicrobial drug. It is important that the in vitro susceptibility test methods and susceptibility test interpretive criteria for systemic antibacterial or antifungal drugs be reviewed on a regular basis and updated to reflect the most current information. The development of new mechanisms of resistance in bacteria or fungi may result in decreased susceptibility to a particular drug. Decreased susceptibility may raise efficacy or safety concerns when out-of-date susceptibility test interpretive criteria are used in guiding the treatment of patients.

Historically, susceptibility test interpretive criteria have been contained in the Microbiology subsection of antimicrobial drug labeling, and there have been significant challenges associated with ensuring that this information is up-to-date in individual antimicrobial drug labels. For some time, FDA and other stakeholders have recognized that susceptibility test interpretive criteria standards established by nationally or internationally recognized standard development organizations (SDOs) can be useful sources of information to identify and update susceptibility test interpretive criteria.

Section 511A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360a–2), as added by section 3044 of the Cures Act (Pub. L. 114–255), was signed into law on December 13, 2016. This provision clarifies FDA's authority to identify and efficiently update susceptibility test interpretive criteria, including through the recognition by FDA of standards established by SDOs. It also clarifies that sponsors of AST devices may rely upon listed susceptibility interpretive criteria to support premarket authorization of their devices, provided they meet certain conditions, which provides for a more streamlined process for incorporating up-to-date information into such devices.

II. Susceptibility Test Interpretive Criteria Website

Section 511A of the FD&C Act requires FDA to establish within 1 year after the date of enactment of the Cures Act an Interpretive Criteria Website that contains a list of FDA-recognized susceptibility test interpretive criteria standards, as well as other susceptibility test interpretive criteria identified by FDA. FDA is announcing the establishment of this Interpretive Criteria Website, which can be found here: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm.*

This website recognizes susceptibility test interpretive criteria established by an SDO that fulfills the requirements under section 511A(b)(2)(A) of the FD&C Act; identifies when FDA does not recognize, in whole or in part, susceptibility test interpretive criteria established by an SDO; and lists susceptibility test interpretive criteria identified by FDA outside the SDO process. The susceptibility test interpretive criteria listed by FDA on the Interpretive Criteria Website are deemed to be recognized as a standard under section 514(c)(1) of the FD&C Act (21 U.S.C. 360d(c)(1)).

At least every 6 months after the establishment of the Interpretive Criteria Website, FDA will publish on the Interpretive Criteria Website a notice recognizing new or updated susceptibility test interpretive criteria standards, or parts of standards; withdrawing recognition of susceptibility test interpretive criteria standards, or parts of standards; and making any other necessary updates to the lists published on the Interpretive Criteria Website. Once a year FDA will compile the notices from that year and publish them in the **Federal Register** and provide for public comment. If comments are received, FDA will review those comments and make any updates to the recognized standards or susceptibility test interpretive criteria as