ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Annex I: Transmittal form under Article 12(2)	54	41	1	2,214
Annex II: Acknowledgment form under Article 12(3)	54	81	.5	2,187
Annex A: Application for Recognition or Recognition and Enforcement, including restricted information on the applicant	54	16	.5	432
Annex A: Abstract of Decision	54	4	1	216
Annex A: Statement of Enforceability of Decision	54	16	0.17	147
Annex A: Statement of Proper Notice	54	4	.5	108
Annex A: Status of Application Report—Article 12	54	34	.33	606
Annex B: Application for Enforcement of a Decision Made or Recognized in the Requested State, including restricted information on the applicant	54	17	.5	459
Annex B: Status of Application Report—Article 12	54	33	.33	588
Annex C: Application for Establishment of a Decision, including restricted information on the Applicant	54	4	.5	108
Annex C: Status of Application Report—Article 12	54	8	.33	143
Annex D: Application for Modification of a Decision, including Restricted Information on the Applicant	54	4	.5	108
Annex D: Status of Application Report—Article 12	54	8	.33	143
Annex E: Financial Circumstances Form	54	41	2	4,428
Annex F: Request for Specific Measures—Article 7(1)	54	2	.17	18
Annex F: Request for Specific Measures—Response—Article 7(1)	54	8	.17	73

Estimated Total Annual Burden Hours: 11,978.

Comments: 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.

Authority: 42 U.S.C. 654(20) and 666(f).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–16068 Filed 7–26–22; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0995]

Ivax Pharmaceuticals, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Chloramphenicol Capsules, 250 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of abbreviated new drug application (ANDA) 062247 for chloramphenicol capsules, 250 milligrams (mg), held by Ivax Pharmaceuticals, Inc. (Ivax). Ivax requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of July 27, 2022.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: On April 28, 1980, FDA approved ANDA 062247 for chloramphenicol capsules, 250 mg, an antibiotic indicated to treat only serious infections for which less potentially dangerous drugs are ineffective or contraindicated. CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg (ANDA 060591), was the basis of submission for Ivax's ANDA 062247 for chloramphenicol capsules, 250 mg. In a **Federal Register** notice dated July 13, 2012 (77 FR 41412), FDA determined under 21 CFR 314.161 that CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg (ANDA 060591), was withdrawn for safety reasons and that additional nonclinical and possibly clinical studies of safety and efficacy would be necessary before CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, could be considered for reintroduction to the market. The holders of approved applications for chloramphenicol capsules, 250 mg, had ceased marketing of the drug products before July 13, 2012.

On March 29, 2013, Ivax requested that FDA withdraw approval of ANDA 062247 for chloramphenicol capsules, 250 mg. On June 17, 2021, Ivax requested that FDA withdraw approval of ANDA 062247 for chloramphenicol capsules, 250 mg, specifically under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. For the reasons discussed above, and pursuant to the application holder's request under 314.150(d), approval of ANDA 062247 for chloramphenicol capsules, 250 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of chloramphenicol capsules, 250 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: July 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16077 Filed 7–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3132]

General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products; 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 final guidance for industry entitled ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.'' This guidance is intended to assist sponsors of investigational new drug applications (INDs) and applicants of new drug applications (NDAs), biologics license applications (BLAs), and supplements to such applications who are planning to conduct clinical studies in neonatal populations. This guidance finalizes the draft guidance of the same title issued on August 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on July 27, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–3132 for ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.'' 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 this 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 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Elimika Pfuma Fletcher, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2162, Silver Spring, MD 20993, 301–796–3473, *Elimika.Fletcher@fda.hhs.gov* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.'' This guidance is intended to assist sponsors of INDs and applicants of NDAs, BLAs, and supplements to such applications who are planning to conduct clinical studies in neonatal populations.

In 2012, the Best Pharmaceuticals for Children Act (Pub. L. 107–109) (BPCA)