

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 050460	AMOXIL	Amoxicillin	125 mg/5mL; 50 mg/ mL; 250 mg/5 mL.	for Suspension; Oral	GlaxoSmithKline.
NDA 050460	LAROTID	Amoxicillin	50 mg/mL	for Suspension; Oral	GlaxoSmithKline.
ANDA 072652	ALBUTEROL SUL- FATE.	Albuterol Sulfate	EQ 0.083% base	Solution; Inhalation ...	Mylan Specialty L.P.
ANDA 075117	ORAPRED	Prednisolone Sodium Phosphate.	EQ 15 mg base/5 mL	Solution; Oral	Concordia Pharma- ceuticals Inc.
ANDA 075385	BUSPIRONE HY- DROCHLORIDE.	Buspirone Hydro- chloride.	5 mg; 10 mg; 15 mg	Tablet; Oral	Teva Pharma- ceuticals USA, Inc.
ANDA 078665	LEVONORGESTREL	Levonorgestrel	0.75 mg	Tablet; Oral	Watson Labs.
ANDA 087811	PHRENILIN	Acetaminophen; Butalbital.	325 mg; 50 mg	Tablet; Oral	Valeant Pharma- ceuticals Inter- national Inc.
ANDA 088825	BUTALBITAL, ACET- AMINOPHEN AND CAFFEINE.	Acetaminophen; Butalbital; Caffeine.	325 mg; 50 mg; 40 mg.	Capsule; Oral	Gilbert Labs.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1064]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application for participation in the Medical Device Fellowship Program.

DATES: Submit either electronic or written comments on the collection of information by November 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-N-1064] for “Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program.”

Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the

Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments

received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), 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 extension 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.

Application for Participation in the Medical Device Fellowship Program—OMB Control Number 0910-0551—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the Medical Device Fellowship Program will allow FDA’s Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application Form (FDA 3608)	250	1	250	1	250

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

Dated: August 30, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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