DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4590]

Morton Grove Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 21 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 21 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 2, 2020.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040759	Phenytoin Sodium Capsules, 30milligrams (mg) (Extended)	Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 062349	Nystatin Oral Suspension, 100,000 units/milliters (mL)	G&W Laboratories, Inc., 301 Helen St., South Plainfield, NJ 07080.
ANDA 062483	Griseofulvin V (griseofulvin microsize) Oral Suspension, 125 mg/5 mL.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 063264	Amikacin Sulfate Injection USP, Equivalent to (EQ) 250 mg base/mL.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 072655	Amantadine Hydrochloride (HCl) Syrup USP, 50 mg/5 mL	G&W Laboratories, Inc.
ANDA 074176	Cimetidine HCl Oral Solution, EQ 300 mg base/5 mL	Do.
ANDA 075366	Sotalol HCl Tablets USP 80 mg, 120 mg, 160 mg, and 240 mg.	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 075887	Fluvoxamine Maleate Tablets, 25 mg, 50 mg, and 100 mg	Do.
ANDA 076709	Fentanyl Extended-Release Film, 25 micrograms (mcg)/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr.	Actavis Laboratories UT, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc, 577 Chipeta Way, Salt Lake City, UT 84108.
ANDA 076841	Mesalamine Enema, 4 grams (gm)/60 mL	G&W Laboratories, Inc.
ANDA 077062	Fentanyl Extended-Release Film, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr.	Mayne Pharma LLC, 1240 Sugg Parkway, Greenville, NC 27834.
ANDA 078426	Zolpidem Tartrate Tablets, 5 mg and 10 mg	Morton Grove Pharmaceuticals Inc.
ANDA 078653	Ranitidine HCl Tablets USP, EQ 150 mg base	Do.
ANDA 078701	Ranitidine HCl Tablets USP, EQ 150 mg base and EQ 300 mg base.	Do.
ANDA 078884	Ranitidine HCl Tablets USP, EQ 75 mg base	Do.
ANDA 087811	Phrenilin (acetaminophen and butalbital) Tablets, 325 mg/50 mg.	Bausch Health US, LLC.
ANDA 088761	Prometh VC Plain (promethazine HCl and phenylephrine HCl) Syrup, 5 mg/5mL, and 6.25 mg/5 mL.	G&W Laboratories, Inc.
ANDA 088762	Prometh w/Dextromethorphan (promethazine HCl and dextromethorphan hydrobromide) Syrup, 6.25 mg/5 mL and 15 mg/5 mL.	Do.
ANDA 090786	Carbidopa, Entacapone, and Levodopa Tablets, 12.5 mg/200 mg/50 mg.	Morton Grove Pharmaceuticals Inc.
ANDA 091267	Donepezil HCl Tablets, 5 mg and 10 mg	Do.
ANDA 201947	Morphine Sulfate Oral Solution, 10 mg/5 mL and 20 mg/5 mL.	VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771.

Do = Ditto.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 2, 2020. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 2, 2020 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25946 Filed 11–29–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3995]

Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Information on Pediatric Uses of Medical Devices

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 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 information collection associated with the requirement for submission of information on pediatric subpopulations that suffer from a disease or condition that a device is intended to treat, diagnose, or cure.

DATES: Submit either electronic or written comments on the collection of information by January 31, 2020.

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 31, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 31, 2020. 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–2016–N–3995 for ''Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure.'' 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.

- 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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 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.

Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure Under Section 515A of the Federal Food, Drug, and Cosmetic Act—21 CFR 814

OMB Control Number 0910–0748—Extension

Section 515A(a) of the Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1) (FD&C Act) requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

These requirements apply to applicants who submit humanitarian device exemption requests (HDEs), premarket approval applications (PMAs) or PMA amendments or supplements, or a product development protocol (PDP).

FDA expects to receive approximately 47 original PMA/PDP/HDE applications each year, 1 of which FDA expects to be HDEs. This estimate is based on the average of FDA's receipt of new PMA applications. The Agency estimates that 11 of the estimated 47 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The Agency also expects to receive approximately 928 supplements that will include the pediatric use information required by section 515A(a) of the FD&C Act and part 814 (21 CFR part 814).

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and part 814. We believe that because the applicant is required to organize and submit only readily available information, no more than 8 hours will be required to comply. Furthermore, because supplements may include readily available information on pediatric populations by referencing a previous submission, FDA estimates the average time to obtain and submit the required information is a supplement to be 2 hours. FDA estimates that the total estimated burden is 2,392 hours.

Additionally, the guidance document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff'' describes how to compile and submit the readily available pediatric use information required under section 515A(a) of the FD&C Act. Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A(a) of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric information in an original PMA or PDP—814.20(b)(13)	11	1	11	8	88
Pediatric information in a PMA amendment—814.37(b)(2)	5	1	5	8	40
Pediatric information in a PMA supplement—814.39(c)(2)(i)	928	1	928	2	1,856
Pediatric information in an HDE—814.104(b)(6)	1	1	1	8	8
Pediatric information for uses outside approved indication	800	1	800	.5	400
Total					2,392

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

Our estimated burden and corresponding responses reflect the requirements under section 515A(a) of the FD&C Act, in addition to the submission of data related to pediatric uses outside an approved indication, as described in the guidance document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff.'' OMB previously approved the information collection related to uses outside an approved indication under OMB control number 0910–0762. As the information collection uses the same data and relies upon the same legal authority as OMB control number 0910–0748, we have discontinued OMB control number 0910–0762 and merged the information collection accordingly. Additionally, we have altered the title of the collection to reflect all collections of pediatric uses.

Our estimated burden for the information collection reflects an overall increase of 632 hours and a corresponding increase of supplements and of uses outside of approved indications. We attribute this adjustment to an increase in the number of supplements we received over the last 5 years and merging data from discontinued OMB control number 0910–0762.

Dated: November 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25980 Filed 11–29–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Patient Survey, OMB No. 0915–0368—Reinstatement

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments