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Dated: December 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26704 Filed 12–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–2659]

Determination That NOROXIN (Norfloxacin) Tablets, 400 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that NOROXIN (norfloxacin) tablets, 400 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for norfloxacin tablets, 400 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NOROXIN (norfloxacin) tablets, 400 mg, is the subject of NDA 019384, held by Merck & Company, Inc. (Merck), and initially approved on October 31, 1986. NOROXIN is indicated for the treatment of adults with the following infections caused by susceptible strains of certain designated microorganisms: Uncomplicated urinary tract infections (including cystitis), uncomplicated urethral and cervical gonorrhea, and prostatitis.

In a letter dated October 13, 2015, Merck notified FDA that NOROXIN (norfloxacin) tablets, 400 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of October 4, 2016 (81 FR 68427), FDA announced that it was withdrawing approval of NDA 019384, effective November 3, 2016.

Jubilant Generics Ltd. submitted a citizen petition dated April 27, 2017 (Docket No. FDA–2017–P–2659), under 21 CFR 10.30, requesting that the Agency determine whether NOROXIN (norfloxacin) tablets, 400 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NOROXIN (norfloxacin) tablets, 400 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NOROXIN (norfloxacin) tablets, 400 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NOROXIN (norfloxacin) tablets, 400 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NOROXIN (norfloxacin) tablets, 400 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to NOROXIN (norfloxacin) tablets, 400 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26693 Filed 12–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–4079]

Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements; 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 guidance for industry entitled ''Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.'' The guidance clarifies the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for human prescription drugs, including prescription biological products, and for animal prescription

drugs. This guidance finalizes the revised draft guidance issued on November 20, 2013 (''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling'').

FDA is also announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: The announcement of the guidance is published in the **Federal Register** on December 12, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—New and title ''Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.'' Also, include the FDA docket number found in brackets in the heading of this document.

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–1999–D–4079 for ''Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements; Guidance for Industry; Availability.'' 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 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 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; or the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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: *Regarding human prescription drugs:* Sheila Ryan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3320, Silver Spring, MD 20993–0002, 301–796–1200. *Regarding human prescription biological products:* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911. *Regarding animal prescription drugs:* Thomas Moskal, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6251.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.'' This guidance clarifies the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for human prescription drugs, including prescription biological products, and for animal prescription drugs. The disclosure of the product

name in promotional labeling and advertisements for all human prescription drugs, including prescription biological products, and animal prescription drugs is important for the proper identification of such products to ensure their safe and effective use.

The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and for prescription animal drugs are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h) and 202.1(b), (c), and (d)).

The recommendations in this guidance pertain to product names in traditional print promotional labeling and advertisements (*e.g.,* journal ads, detail aids, brochures), audiovisual promotional labeling (*e.g.,* videos shown in a health care provider's office), broadcast advertisements (*e.g.,* television advertisements, radio advertisements), and electronic and computer-based promotions (*e.g.,* internet, social media, emails, CD–ROMs, DVDs).

In the **Federal Register** of November 20, 2013 (78 FR 69691), FDA announced the availability of the revised draft guidance entitled ''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.'' FDA received one comment on the revised draft guidance, which requested additional clarification on the individual recommendations in the guidance, and FDA considered this comment as the guidance was finalized. In addition to a title change and editorial changes made primarily for clarification, the guidance has been revised to clarify certain concepts discussed in the revised draft guidance and to provide examples illustrating prominence issues.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements.'' 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. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. The information collection requests in support of the guidance are discussed below. Specifically, the guidance discusses the requirement in FDA's regulations for prescription drug promotional labeling and advertisements to include the established name in conjunction with the proprietary name, and explains FDA recommendations that:

- Firms should include the established name at least once per page or spread where the proprietary name most prominently appears.
- The established name should be placed either directly beside or below the proprietary name without any intervening matter.
- The size of the established name should be at least half the size of the presentation of the proprietary name wherever the established name is required.
- For superimposed text that is equivalent to a headline or tagline, the established name should be presented alongside the most prominent presentation of the proprietary name in audiovisual promotional materials (promotional labeling and broadcast advertisements).
- For electronic and computer-based promotion, the established name should accompany the proprietary name at least once per Web page, and this should generally be where the proprietary name most prominently appears on the Web page.

Thus, the guidance recommends that firms disclose certain information to others to fulfill the product name placement requirements found in FDA's regulations. This ''third-party disclosure'' constitutes a ''collection of information'' under the PRA. Disclosures in advertising pursuant to 21 CFR 202.1 are covered by an existing information collection (OMB control number 0910–0686), so this information collection request covers only disclosures in labeling in accordance with 21 CFR 201.10(g) and (h).

In the **Federal Register** of November 20, 2013, FDA published a 60-day notice requesting public comment on the proposed collection of information and the estimated annual burden for third party disclosure. FDA received no comments in response to the four information collection topics solicited in the notice. FDA has received more up-to-date submission data since the 60-day notice published, therefore, we have adjusted our estimates of respondents and disclosures accordingly. The estimated amount of time per disclosure has not changed. We therefore estimate the burden associated with the information collection as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Guidance recommendations	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
Disclosures Related to Product Name Placement, Size, and Prominence	407	256.4	104,358	3	313,074

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

As reflected in table 1, we provide an estimate of the annual third-party disclosure burden associated with this collection of information. The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and animal prescription drugs are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h); 202.1(b), (c) and (d); and 610.62). Using calendar year 2015 data, FDA estimates that, for prescription human and animal drugs and biological products, approximately 407 firms disseminate approximately 104,358 advertisements and promotional pieces each year. We further estimate that the burden hours associated with the regulatory requirements would be approximately 3 hours per disclosure.

FDA is issuing this final guidance subject to OMB approval of the information collection. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the **Federal Register** announcing OMB's decision to

approve, modify, or disapprove the collections of information, including OMB control number(s) for newly approved collections.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information associated with 21 CFR 202.1 have been approved under OMB control number 0910–0686.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *https://www.regulations.gov.*

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26725 Filed 12–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0015]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Products Development; Food and Drug Administration Orphan Drug Designation Request Form and The Common European Medicines Agency/Food and Drug Administration Form for Orphan Medicinal Product Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 11, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Products Development; Food and Drug Administration Orphan Drug Designation Request Form and The Common European Medicines Agency/Food and Drug Administration Form for Orphan Medicinal Product Designation (Formerly Orphan Drugs; Common European Medicines Agency/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671))—21 CFR Part 316

OMB Control Number 0910–0167—Extension

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360aa–360dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the FD&C Act and sets forth procedures FDA will use in administering the FD&C Act with regard to orphan drugs.

Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Based on past experience, FDA estimates that there will be one respondent to §§ 316.10, 316.12, and 316.14 requiring 50 hours of human resources annually.

Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.21 specifies content of a request for orphan drug designation required for verification of orphan-drug status. Section 316.26 allows an applicant to amend the applications under certain circumstances. Based on past experience, FDA estimates 496 respondents to §§ 316.20, 316.21, and 316.26, requiring 83,700 hours of human resources annually.

The Common EMEA/FDA Application for Orphan Medicinal Product Designation form for orphan designation of drugs intended for rare diseases or conditions (Form FDA 3671) is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from both the European Commission and FDA by reducing the burden of preparing separate applications to meet the regulatory requirements in each jurisdiction. It highlights the regulatory cooperation between the United States and the European Union mandated by the Transatlantic Economic Council. The FDA Orphan Drug Designation Request Form (Form FDA 4035) is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from only FDA. The form is a simplified method for sponsors to provide only information required by 21 CFR 316.20 for FDA to make a decision. Based on past experience, FDA estimates there will be 496 respondents using the form requiring 19,840 hours of human resources annually.

Section 316.22 specifies requirement of a permanent resident agent for foreign sponsors. Based on past experience, FDA estimates 70 respondents requiring 140 hours of human resources annually.