April 16, 2019, **Federal Register**, 84 FR 15680, and amended May 23, 2019, **Federal Register**, 84 FR 23832, effective January 1, 2021.

- The addition of instructions for MA–PDs to enter text in the free text field ''why did we deny your request?'' when they have determined that the requested drug being denied is covered under Part D.

Form Number: CMS–10003 (OMB control number: 0938–0829); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 694; *Total Annual Responses:* 9,373,200; *Total Annual Hours:* 1,561,575. (For policy questions regarding this collection contact Staci Paige at 410–786–1943.)

Dated: July 5, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–14719 Filed 7–9–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2338]

Apotex, Inc.; Withdrawal of Approval of 31 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of 31 abbreviated new drug applications (ANDAs) held by Apotex, Inc. (Apotex). Apotex, through its U.S. agent, has requested withdrawal of these applications and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of July 10, 2019.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: FDA approved the following ANDAs on the dates indicated in the table, for the conditions of use found in the reference listed drug for each application:

ANDA	Date of approval	Name of drug product
040774	October 3, 2007	Hydrochlorothiazide Tablets USP, 25 milligrams (mg) and 50 mg.
065507	July 13, 2011	Azithromycin Tablets, 250 mg.
065508	July 13, 2011	Azithromycin Tablets, 600 mg.
065509	July 13, 2011	Azithromycin Tablets, 500 mg.
078389	May 16, 2008	Hydrochlorothiazide Capsules, 12.5 mg.
078841	June 2, 2011	Donepezil Hydrochloride Tablets, 5 mg and 10 mg.
090150	October 6, 2010	Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg, 100 mg/12.5mg, and 100 mg/25 mg.
090419	April 22, 2009	Mycophenolate Mofetil Capsules, 250 mg.
090463	August 30, 2010	Perindopril Erbumine Tablets, 2 mg, 4 mg, and 8 mg.
090499	April 22, 2009	Mycophenolate Mofetil Tablets, 500 mg.
090790	October 6, 2010	Losartan Potassium Tablets USP, 25 mg, 50 mg, and 100 mg.
091260	August 25, 2011	Cevimeline Hydrochloride Capsules, 30 mg.
091373	April 22, 2011	Naratriptan Tablets USP, 1 mg and 2.5 mg.
091379	November 6, 2012	Sildenafil Citrate Tablets, 20 mg.
200164	September 25, 2012	Tolterodine Tartrate Tablets, 1 mg and 2 mg.
200832	October 15, 2012	Irbesartan Tablets USP, 75 mg, 150 mg, and 300 mg.
200878	April 20, 2012	Verapamil Hydrochloride Extended-Release Tablets USP, 120 mg, 180 mg, and 240 mg.
201294	August 3, 2012	Montelukast Sodium Tablets, 10 mg.
201503	March 8, 2013	Cabergoline Tablets, 0.5 mg.
201505	October 15, 2012	Irbesartan and Hydrochlorothiazide Tablets USP, 150 mg/12.5 mg, and 300 mg/12.5 mg.
201508	August 3, 2012	Montelukast Sodium Chewable Tablets, 4 mg and 5 mg.
201950	September 12, 2013	Rasagiline Mesylate Tablets, 0.5 mg and 1 mg.
202078	May 14, 2013	Zolmitriptan Tablets, 2.5 mg and 5 mg.
202079	January 10, 2014	Candesartan Cilexetil Tablets, 4 mg, 8 mg, 16 mg, and 32 mg.
202244	December 31, 2012	Rizatriptan Benzoate Tablets, 5 mg and 10 mg.
202476	May 14, 2013	Zolmitriptan Orally Disintegrating Tablets, 2.5 mg and 5 mg.
202477	July 1, 2013	Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg and 10 mg.
202884	December 4, 2012	Candesartan Cilexetil and Hydrochlorothiazide Tablets, 16 mg/12.5 mg, 32 mg/12.5 mg, and 32 mg/25 mg.
203021	May 22, 2012	Nevirapine Tablets USP, 200 mg.
203026	March 21, 2013	Valsartan and Hydrochlorothiazide Tablets USP, 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg.
205258	April 3, 2014	Nevirapine Extended-Release Tablets, 400 mg.

However, after these drugs were approved, FDA became aware of concerns involving material manufactured at two Apotex facilities, at least one of which was named in each of these applications. The facilities involved were Apotex Private Research Ltd. (Federal Employer Identification (FEI) number: 3006076314) and Apotex Pharmachem India Private Ltd. (FEI: 3005466325). The application numbers for the impacted ANDAs are listed above. In January 2018, Apotex requested withdrawal of the above ANDAs and waived its opportunity for a hearing. FDA interprets this withdrawal request as a request under § 314.150(d) (21 CFR 314.150(d)).

Therefore, for the reasons discussed above, and pursuant to Apotex's request, FDA is withdrawing approval

of the ANDAs in the table above, and all amendments and supplements thereto, under § 314.150(d). In each case, approval of the entire application is withdrawn, including any approved strengths inadvertently missing from the table. Distribution of the products listed in the table above in 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 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14660 Filed 7–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1747]

Risk Evaluation and Mitigation Strategies: Modifications and Revisions; 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 ''Risk Evaluation and Mitigation Strategies: Modifications and Revisions.'' This guidance provides information on how FDA will define and process submissions for modifications and revisions of risk evaluation and mitigation strategies (REMS), as well as information on what types of changes to approved REMS will be considered modifications or revisions of the REMS. The guidance also provides instructions to application holders related to procedures for submission of REMS modifications and revisions to FDA as well as different timeframes for FDA's review of and action on such changes. The definitions of REMS modifications and revisions apply to all types of REMS. This guidance updates the guidance of the same name, issued April 7, 2015, including finalizing the portion that sets forth the submission procedures for REMS revisions.

DATES: The announcement of the guidance is published in the **Federal Register** on July 10, 2019.

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–2014–D–1747 for ''Risk Evaluation and Mitigation Strategies: Modifications and Revisions.'' 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/FR2015-09-18/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 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 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: Vaishali Jarral, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6480, Silver Spring, MD 20993–0002, 301–796–4248; or Stephen Ripley, Center for