Issuers in the small group market may use the draft federal standard small group notices released in the June 26, 2014 bulletin ''Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group or Individual Market'', or any forms of the notice otherwise permitted by applicable laws and regulations. States that are enforcing the guaranteed renewability provisions of the Affordable Care Act may develop their own standard notices for product discontinuances, renewals, or both, provided the state-developed notices are at least as protective as the federal standard notices. *Form Number:* CMS–10527 (OMB control number 0938–1254); *Frequency:* Annually; *Affected Public:* Private Sector, State Governments; *Number of Respondents:* 1,805; *Total Annual Responses:* 7,420; *Total Annual Hours:* 90,331. For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.

Dated: July 5, 2019.

William N. Parham, III,

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

[FR Doc. 2019–14693 Filed 7–9–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10003]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 9, 2019.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection*: Revision with change of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medical Coverage (or Payment) (NDMCP); *Use:* Section 1852(g)(1)(B) of the Social Security Act (the Act) requires Medicare health plans to provide enrollees with a written notice in understandable language of the reasons for the denial and a description of the applicable appeals processes. Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue the Notice of Denial of Medical Coverage (or Payment) (NDMCP) when a request for either a medical service or payment is denied, in whole or in part. Additionally, the notices inform Medicare enrollees of their right to file an appeal, outlining the steps and timeframes for filing. All Medicare health plans are required to use these standardized notices. In 2013, Medicaid appeal rights were integrated into form CMS–10003 for beneficiaries who are eligible for Medicare and full Medicaid benefits under a State Medicaid plan. These appeal rights are provided in instances where a Medicare health plan enrollee receives full benefits under a State Medical Assistance (Medicaid) program being managed by the plan and the plan denies a service or item that is also subject to Medicaid appeal rights.

Changes to the collection from the 60-day package to the 30-day package include:

- Removal of language related to State Fair Hearings to comply with the change in Medicaid managed care rules at 42 CFR 438.402(c)(1)(i), effective 2017, that all Medicaid managed care denials must now first have a plan-level review before a State Fair Hearing can be requested.
- Updates to comply with the Medicare Advantage final rule, published May 23, 2019, **Federal Register**, 84 FR 23832, effective January 1, 2020, regarding the change in timeframes for Medicare Advantage appeals related to Part B drugs.
- Removing the option to delete sections related to expedited payment requests (if applicable); plans are to leave all language regarding fast appeals. Text has been added to the notice informing enrollees they do not have a right to request an expedited appeal if they are asking to be paid back for an item or service already received (42 CFR 422.570(a)).
- The addition of language in the instructions that ''applicable integrated plans'' should follow notification requirements under final rule published

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]

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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