equivalence) for a new tobacco product (section 905(j)(1)A)(i) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(i))).

The guidance recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: Dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

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

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	1,000	1	1,000	5	5,000

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

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the Pre-Existing status of a tobacco product under the guidance is not required and also on the number of Pre-Existing tobacco product submissions received from 2011 to October 2021. For deemed products that met the definition of a new tobacco product and were on the market as of August 8, 2016 (when the deeming rule took effect), FDA issued a compliance policy; this, in effect, provided more time for manufacturers of these products to submit their applications for marketing authorization. The deadline for the submission of applications for these products has now passed. As the result of a court order (and a subsequent extension due to the unique circumstances of the COVID–19 pandemic), applications for deemed new tobacco products on the market at that time were due to FDA by September 9, 2020.[2] The court order also provided a 1-year period during which products with timely filed applications might remain on the market pending FDA review. The number of hours to gather the evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 5,000 hours annually to respond to this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 2, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26652 Filed 12–8–21; 8:45 am]

BILLING CODE 4164–01–P

[2] On August 19, 2020, the U.S. District Court for the District of Columbia issued a ruling, in part, to prohibit FDA enforcement of the Tobacco Control Act's premarket authorization requirement for premium cigars until after the agency considers developing a streamlined substantial equivalence process specifically for premium cigars. Accordingly, FDA will not enforce the premarket review requirement against manufacturers of premium cigars that do not submit premarket applications for these products by the September 9, 2020 deadline.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1194]

Fresenius Kabi Deutschland GmbH; Withdrawal of Approval of New Drug Application of Hydroxyethyl Starch

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) BN 070012/0022 for VOLUVEN (6 Percent Hydroxyethyl Starch 130/0.4 in 0.9 Percent Sodium Chloride Injection), held by Fresenius Kabi Deutschland GmbH. Fresenius Kabi Deutschland GmbH requested in writing that the Agency's approval of the application be withdrawn because the drug is no longer being marketed and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of January 10, 2022.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, 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.

SUPPLEMENTARY INFORMATION: Fresenius Kabi Deutschland GmbH, Bad Homburg, Germany (Authorized U.S. Agent: Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047), has requested that FDA withdraw approval of NDA BN 070012 sequence 0022, pursuant to § 314.150(c) (21 CFR 314.150(c)), because the drug is no longer being marketed. By its request, Fresenius Kabi Deutschland GmbH, has also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Application No.	Proprietary name
NDA BN 070012/0022.	VOLUVEN (6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection)

Therefore, approval of the application listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 10, 2022. Introduction or delivery for introduction into interstate commerce for products without a new drug application violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). The drug product that is listed in the table above that is in inventory on January 10, 2022 may continue to be dispensed until the inventory has been depleted or the drug product has reached its expiration date or otherwise becomes violative, whichever occurs first.

Dated: December 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26648 Filed 12–8–21; 8:45 am]

BILLING CODE 4164–01–P