DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1064]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 December 6, 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 0910–0277. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

State Petitions for Exemption From Preemption

OMB Control Number 0910–0277—Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard-of-identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard-of-identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

In the **Federal Register** of June 15, 2017 (82 FR 27491), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 100.1(d)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form of petition	1	1	1	40	40

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

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, we have received one new petition for exemption from preemption; therefore, we estimate that one or fewer petitions will be submitted annually.

Dated: November 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–3101]

Abbreviated New Drug Applications: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence); Draft 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 revised draft guidance for industry entitled ''ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence).'' FDA is revising the draft guidance because, after issuance of the original draft guidance, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was amended by the FDA Reauthorization Act of 2017, which resulted in changes to the pre-submission of facility information. Pre-submitting facility information enables the Agency to determine whether inspection of a facility is necessary and, if so, to begin inspection planning in advance of an abbreviated new drug application (ANDA) receipt.

DATES: Submit either electronic or written comments on the draft guidance by February 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by January 5, 2018.

ADDRESSES: You may submit comments on any guidance 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.