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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, are the subject of NDA 020911, held by TEVA Branded Pharmaceutical Products R&D, Inc. (TEVA), and initially approved on September 15, 2000. QVAR 40 and QVAR 80 are indicated for the maintenance treatment of asthma as a prophylactic therapy in patients 5 years of age and older.

Aurolife Pharma LLC submitted a citizen petition dated September 6, 2018 (Docket No. FDA–2018–P–3412), under 21 CFR 10.30, requesting that the Agency determine whether QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, were withdrawn from sale for reasons of safety or effectiveness.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§ 314.161 that QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, were withdrawn for reasons of safety or effectiveness. In addition, the petitioner provided information indicating that TEVA made a business decision to discontinue manufacturing of these drug products. We have carefully reviewed our files for records concerning the withdrawal of QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, 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 these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, 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 QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, 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 to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06552 Filed 4–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance: Emergency Use Authorization of Medical Products and Related Authorities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed extension of the collection of information related to emergency use authorizations by the Agency.

DATES: Submit either electronic or written comments on the collection of information by June 3, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 3, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 3, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2012–N–0976 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance: Emergency Use Authorization of Medical Products and Related Authorities.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

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: Under the 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance: Emergency Use Authorization of Medical Products and Related Authorities

OMB Control Number 0910–0595—Extension

The guidance describes the Agency's policies applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b), as amended or added by the Project BioShield Act of 2004 (Pub. L. 108–276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5), 21st Century Cures Act (Pub. L. 114–255), and Public Law 115–92 (2017). The FD&C Act permits the Commissioner to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an emergency use authorization (EUA) must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the FD&C Act, the FDA Commissioner may establish conditions on the authorization. Section 564(e) requires the FDA Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the FDA Commissioner to establish other conditions that he or she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C Act include, for example: Requirements for information dissemination to healthcare providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which

the authorization is issued. Section 564 of the FD&C Act also gives the FDA Commissioner authority to establish other conditions on an authorization that he or she finds to be necessary or appropriate to protect the public health. Additionally, sections 564A and 564B established streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved products without requiring FDA to issue an EUA, including expiration date extension authority.

For purposes of estimating the annual burden of reporting (table 1), FDA has established four categories of respondents: (1) Those who file a request for FDA to issue an EUA or a substantive amendment to an EUA that has previously been issued, assuming that a requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) those who submit a request for FDA to review information/data (*i.e.,* a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) manufacturers who carry out an activity related to an unapproved EUA product (*e.g.,* administering product, disseminating information) who must report to FDA regarding such activity; and (4) public health authorities (*e.g.,* State, local) who carry out an activity (*e.g.,* administering product, disseminating information) related to an unapproved EUA product who must report to FDA regarding such activity or who submit to FDA an expiration date extension request for an approved product.

In some cases, manufacturers directly submit EUA requests. Often a Federal Government entity (*e.g.,* Centers for Disease Control and Prevention, Department of Defense) requests that FDA issue an EUA and submits pre-EUA packages for FDA to review. In many of these cases, manufacturer respondents inform these requests and submissions, which are the activities that form the basis of the estimated reporting burdens. However, in some cases the Federal Government is the sole respondent; manufacturers do not inform these requests or submissions. FDA estimates minimal burden when the Federal Government performs the relevant activities. In addition to variability based on whether there is an active manufacturer respondent, other factors also inject significant variability in estimates for annual reporting burdens. A second factor is the type of product. For example, FDA estimates greater burden for novel therapeutics than for certain unapproved uses of approved products. A third significant factor that injects variability is the type of submission. For example, FDA estimates greater burden for ''original'' EUA and pre-EUA submissions than for amendments to them, and FDA estimates minimal burden to issue an EUA when there is a previously reviewed pre-EUA package or investigational application. For purposes of estimating the reporting burden, FDA has calculated the anticipated burden on manufacturers based on the anticipated types of responses (*i.e.,* estimated manufacturer input), types of product, and types of submission that comprise the described reporting activities.

For purposes of estimating the annual burden of recordkeeping, FDA has also calculated the anticipated burden on manufacturers and public health officials associated with administration of unapproved products authorized for emergency use, recognizing that the Federal Government will perform much of the recordkeeping related to administration of such products (table 2). FDA is not calculating any recordkeeping burden for public health authorities who may need to submit expiration date extension requests, as these entities already maintain records for the products that they stockpile, which would include records of any expiration date request or extension.

The guidance refers to previously approved collections of information. These collections are subject to review by the OMB under the PRA. These collections have been approved as follows: Adverse experience reporting for biological products is approved under OMB control number 0910–0308; adverse drug experience reporting is approved under OMB control number 0910–0230; adverse device experience reporting is approved under OMB control number 0910–0471; investigational new drug (IND) application regulations are approved under OMB control number 0910–0014and investigational device exemption (IDE) reporting is approved under OMB control number 0910–0078; current good manufacturing practices for finished pharmaceuticals are approved under OMB control number 0910–0139, and for devices under OMB control number 0910–0073; applications for marketing a new drug are approved under OMB control number 0910–0001, and for biological products under OMB control number. Any additional burden imposed by this proposed collection would be minimal.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Requests to Issue an EUA or a Substantive Amendment to an Existing EUA	12	2.39	29	45	1,305
FDA Review of a Pre-EUA Package or an Amendment Thereto	32	1.79	57	34	1,938
Manufacturers of an Unapproved EUA Product	12	5.8	70	2	140
Public Health Authorities; Unapproved EUA Product	30	3	90	2	180
Public Health Authorities; Request for Expiration Date Extension	1	1	1	2	2
Total					3,565

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers of an Unapproved EUA Product	12	2	24	25	600
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					870

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

Our estimated annual reporting burden for the information collection reflects an overall increase of 239 hours since our last request for OMB approval. We attribute this adjustment to an increase in the number of submissions we received.

Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06553 Filed 4–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs

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 May 6, 2019.

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 ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs—OMB Control Number 0910–NEW

This information collection request supports recommendations found in the Agency guidance document entitled, ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' The guidance document outlines the requirements and recommendations for manufacturers, packers, and distributors (firms) that may either be the applicant or acting on behalf of the applicant, to make submissions pertaining to promotional materials for human prescription drugs (''drugs'') to the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) and the Advertising and Promotional Labeling Branch (APLB) in the Center for Biologics Evaluation and Research (CBER). References to ''drugs'' in the guidance also include human biological products that fall within the definition of ''drug'' under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)).

The guidance describes the various types of submissions of promotional materials and general considerations for submissions. The guidance discusses the specific aspects of submission of promotional materials using module 1 of the electronic Common Technical Document (eCTD) using version 3.3 or higher of the *us-regional-backbone* file. The guidance does not address the more general requirements for a valid electronic submission using eCTD or the specifications for module 1 of the eCTD. The guidance contains both binding and nonbinding provisions. The provisions that are binding implement section 745A(a) of the FD&C Act (21 U.S.C. 379k–1(a)), which requires that certain submissions be submitted in electronic format specified by FDA, beginning no earlier than 24 months after FDA issues a final guidance specifying such electronic submission format.

The guidance provides recommendations for what to include with each type of submission and the number of copies to include if it is a paper submission. For promotional labeling submitted for advisory comments, including resubmissions, a submission generally includes correspondence stating that it is a request for advisory comments, a clean version of the draft promotional materials, an annotated copy of the promotional materials, and the most current FDA-approved prescribing information (PI); if applicable, a submission also includes the FDA-approved patient labeling or Medication Guide with annotations cross-referenced to the proposed promotional materials and annotated references to support product and disease or epidemiology claims not contained in the PI cross-referenced to the promotional material. Amendments should be submitted if the previous submission to FDA is missing one or more promotional materials or if an incorrect document file was included with a submission in eCTD format. Amendments should include correspondence stating it is an amendment and include the accompanying materials that were previously missing, an annotated copy of the promotional materials that were omitted from a previous submission to FDA, the FDA-approved patient labeling or Medication Guide with annotations