

OMB control number 0910–0844, includes De Novo requests for accessories. We have determined that the burden estimate for “Accessory Classification De Novo Requests” in this ICR (Accessory Classification Requests; OMB control number 0910–0823) is redundant and have, therefore, removed it.

Depending on an accessory’s regulatory history, there are different submission types, tracking mechanisms, and deadlines:

(1) Existing accessory types are those that have been identified in a classification regulation or granted marketing authorization as part of a 510(k), pre-market application (PMA), or De Novo request (approved under OMB control numbers 0910–0120, 0910–0231, and 0910–0844, respectively). Manufacturers with marketing authorization for an existing accessory may request appropriate

classification through a new stand-alone premarket submission (Existing Accessory Request). Upon request, FDA is required to meet with a manufacturer or importer to discuss the appropriate classification of an existing accessory prior to submitting a written request. Existing Accessory Requests will be initially tracked as “Q-submissions” (approved under OMB control number 0910–0756). FDA has a statutory deadline of 85 calendar days to respond to an Existing Accessory Request.

(2) New accessory types are those that have not been granted marketing authorization as part of a 510(k), PMA, or De Novo request. Manufacturers may include new accessories into a 510(k) or PMA with the parent device (New Accessory Request). New Accessory Requests will have the same deadline as the 510(k) or PMA. Therefore, new accessory types should follow the applicable Medical Device User Fee

Amendments of 2017 deadline for the parent submission. The decision for New Accessory Requests will be separate from the decision for the marketing application.

For both Existing and New Accessory Requests, manufacturers must request proper classification of their accessory in the submission and include draft special controls, if requesting classification into class II. The processes that we use to classify an accessory will be like those used for De Novo requests. If FDA grants the Accessory Request, FDA must issue an order establishing a new classification regulation for the accessory type. If FDA denies the Accessory Request, FDA must issue a letter with a detailed description and justification for our determination.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Existing Accessory Request	15	1	15	40	600
New Accessory Request	10	1	10	40	400
Total					1,000

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

We expect to receive approximately 15 Existing Accessory Requests and 10 New Accessory Requests per year. Based on estimates by FDA administrative and technical staff who are familiar with the submission process for accessory classification requests, we estimate that the “Average Burden per Response” for both Existing and New Accessory Requests will be approximately 40 hours per submission.

Our estimated burden for the information collection reflects an overall decrease of 440 hours and an increase of 17 responses. Factors contributing to the revision of the burden estimate include the addition of the two new accessory classification pathways created by FDARA and the removal of redundant burden described earlier in this document.

Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06551 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–2018–P–3412]

Determination That QVAR 40 and QVAR 80 (Beclomethasone Dipropionate HFA) Inhalation Aerosol, 40 Micrograms and 80 Micrograms, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 micrograms (mcg) and 80 mcg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for QVAR 40 and QVAR 80 (beclomethasone dipropionate HFA) inhalation aerosol, 40 mcg and 80 mcg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3507.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs.

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