(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 7, 2016.

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 title Outcomes Evaluation Survey for Graduates of the FDA Commissioner's Fellowship Program. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Survey of Alumni Commissioner's Fellowship Program Fellows—OMB Control Number 0910–NEW

FDA is requesting approval from the Office of Management and Budget to gather information from Alumni Commissioner's Fellowship Program (CFP) Fellows. The information from Alumni CFP Fellows will allow FDA's Office of the Commissioner (OC) to easily and efficiently elicit and review program feedback. The online survey will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their experience with the FDA while a Commissioner's Fellow. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of surveys being misrouted within the Agency mail system. The information gathered by the survey will be used to gain insights into, and to document, impacts that the CFP has had and is having on former CFP fellows and contributions and impacts that the former fellows are making in their current work. The surveys include questions to assess the following measures: Post-fellowship employment (*e.g.,* employment type); number of awards; number of contributions while a CFP fellow (*e.g.,* number of publications, guidances authored or co-authored); and contributions in their field (*e.g.,* list of publications).

In the **Federal Register** of February 24, 2016 (81 FR 9202), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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
Fellowship Program Survey	35	1	35	0.50 (30 minutes)	17.5

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

FDA based these estimates on the number of fellows that have graduated and left the Agency over the past 5 years.

Dated: August 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18711 Filed 8–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2062]

Determination That BENTYL (Dicyclomine Hydrochloride) Syrup and Other Drug Products 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 the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

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 approved 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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under

21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 007961	BENTYL	Dicyclomine Hydrochloride (HCl).	10 milligrams (mg)/5 milliliters (mL).	Syrup; Oral	Aptalis Pharma US, Inc.
NDA 011721	NEPTAZANE	Methazolamide	25 mg; 50 mg	Tablet; Oral	Lederle Laboratories.
NDA 016418	INDERAL	Propranolol HCl	10 mg; 20 mg; 40 mg; 60 mg	Tablet; Oral	Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer Inc.
NDA 021410	AVANDAMET	Metformin HCl; Rosiglitazone Maleate.	500 mg/Equivalent to (EQ) 2 mg base; 500 mg/EQ 4 mg base; 1 g/EQ 2 mg base; 1 g/EQ 4 mg base.	Tablet; Oral	SmithKline Beecham (Cork) Ltd, Ireland.
NDA 021494	AXID	Nizatidine	15 mg/mL	Solution; Oral	Braintree Laboratories, Inc.
NDA 050505	GARAMYCIN	Gentamicin Sulfate.	EQ 2 mg base/mL	Injectable; Intrathecal.	Schering-Plough Corp.
ANDA 061716	GARAMYCIN	Gentamicin Sulfate.	EQ 1 mg base/mL; EQ 40 mg base/mL.	Injectable; Injection.	Schering-Plough Corp.
ANDA 061739	GARAMYCIN	Gentamicin Sulfate.	EQ 10 mg base/mL	Injectable; Injection.	Schering-Plough Corp.
ANDA 080745	ARISTOCORT and ARISTOCORT A.	Triamcinolone Acetonide.	0.5%	Ointment; Topical.	Astellas Pharma US, Inc.
ANDA 083944	KENALOG	Triamcinolone Acetonide.	0.5%	Ointment; Topical.	Delcor Asset Corp.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18707 Filed 8–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0453]

Deciding When To Submit a 510(k) for a Software Change to an Existing Device; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device.'' FDA is issuing this draft guidance document to clarify when a software change in a legally marketed medical device would require that a manufacturer submit a premarket notification (510(k)) to FDA. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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: