cure and (2) the number of affected pediatric patients.

The purpose of this guidance document is to describe the type of information that FDA believes is readily-available to the applicant, and the information FDA believes should be included in a submission to meet the requirements of section 515A(a) of the FD&C Act. The draft version of this guidance was issued on February 19, 2013 (78 FR 11654).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Providing Information about Pediatric Uses of Medical Devices,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1801 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

On January 9, 2014, the Agency submitted a proposed collection of information entitled ''Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug and Cosmetic Act'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0762. The approval expires on March 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 814, subpart B have been approved under OMB control number 0910–0231 and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332.

V. Comments

Interested persons may submit either written comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09897 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0366]

Pilot Program for Center for Devices and Radiological Health Electronic Submission of Premarket Notification Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) is announcing the availability of a CDRH eSubmissions Pilot Program (eSubmissions Pilot), which will be a new pathway that will guide the user through constructing and submitting their 510(k) submissions electronically without the requirement for submitting a hard copy or a compact disc. Participation in the eSubmissions Pilot is open to applicants whose device submissions would be reviewed in either of two branches in CDRH's Office of Device Evaluation (ODE), the Cardiac Diagnostic Devices Branch and the Peripheral Interventional Devices Branch, and is limited to unbundled, traditional 510(k) submissions for classified devices only. The eSubmissions Pilot will use the existing eSubmitter software for data acquisition and the existing Electronic Submission Gateway (ESG) for submitting (the eSubmissions Pilot is not intended to evaluate the existing eSubmitter software or the existing ESG). The eSubmissions Pilot is intended to provide industry and CDRH staff the opportunity to evaluate the 510(k) eSubmission with regards to the content (wording of questions, help text and guides), layout, and flow of the questions.

DATES: FDA will begin accepting requests to participate in the eSubmissions Pilot immediately. See the ''Procedures'' section for instructions on how to submit a request.

FOR FURTHER INFORMATION CONTACT: Patrick Axtell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1566, Silver Spring, MD 20993–0002, *eSubpilot@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has been moving toward transforming all regulatory submissions from paper to electronic methods. Since January 1999, FDA has accepted voluntary electronic submissions for certain types of regulatory submissions. FDA presently utilizes eSubmitter as a platform for submitting many types of submissions across several Centers. The eSubmitter platform contains templates for many types of submissions specific to those Centers and any template can be chosen by the user for constructing and submitting the appropriate type of submission. The 510(k) eSubmission program introduces a new template in eSubmitter for use in submitting 510(k)s to ODE.

FDA presently utilizes the ESG for the receipt and processing of many types of electronic regulatory submissions (*http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*). The ESG automates the receipt, acknowledgment, routing and notification of electronic submissions via the Internet and meets FDAs standards of electronic information exchange.

The benefits to industry of this pilot program include, but are not limited to:

• Application of the ''Refuse to Accept Policy for 510(k)s'' (RTA) guidance document will be waived during the pilot (i.e., no submissions submitted via the software will be subject to an acceptance review as outlined in the RTA guidance).

• A guided interface that leads the sponsor through the process of constructing and submitting their 510(k) submissions. Built into the software are a number of features that ensure appropriate regulatory submission standards and recommendations are met or considered. Further, software features will prompt the inclusion of information that will avert some of the common procedural and administrative issues reviewers find during their reviews.

• The 510(k) eSubmissions are expected to decrease both the time spent by industry creating and submitting the 510(k).

• The 510(k) eSubmission process may also reduce the number of questions asked by FDA to which the applicant must officially respond.

• Since the 510(k) submission process will be completely electronic, time will not be lost in physical transit of the submission to FDA.

• The eSubmission software is intended to be a guide for users to instruct them as to what is required and recommended when submitting a 510(k), and will act as an aid for learning about the process. The use of electronic signatures will allow sponsors to legally sign documents without the need for printing, scanning and uploading.

The benefits to FDA include, but are not limited to:

• A reduction in required resources and time spent in processing the submission for review.

• Easier and faster reviews due to a standardized submission structure.

510(k) eSubmissions also support the Secretary's health IT priorities to harness information technology to improve health care and patient safety. The information learned and experiences gained from the eSubmissions Pilot will be used to optimize the process by which data and documents are obtained and ensure that the software infrastructure functions properly and electronic signatures work as intended.

II. CDRH eSubmissions Pilot

The eSubmissions Pilot presents a voluntary process to interested sponsors. This notice outlines: (1) The guiding principles underlying the eSubmissions Pilot; (2) the scope of the eSubmissions Pilot; and (3) the procedures CDRH intends to follow for the eSubmissions Pilot. The eSubmission process works similarly to commercially available tax preparation software packages such that it guides the sponsor through the submission process. Help text, links, embedded guides, and other aids are intended to assist the user and allow novice 510(k) submitters to navigate through the process of submitting a 510(k) submission. The software will consist of textual suggestions and questions designed to obtain all of the data FDA needs to review the submission and ensure no required data are omitted. FDA intends to collect data via text fields, checkboxes, dropdown menus, and, where it would be burdensome to collect data via these methods, file attachments. For example, FDA intends to collect much of the administrative data as well as basic information, such as the Indications for Use, via the software interface, not via file attachments. However, instruction manuals, software documentation, performance testing and other large documents may be attached.

A. Guiding Principles

The following basic principles underline the eSubmissions Pilot described in this document. CDRH intends that these principles create a common understanding between the sponsor and CDRH about the goals and parameters of the eSubmissions Pilot:

1. FDA believes the use of the eSubmission process will result in administratively complete 510(k) submissions and will not be conducting a separate acceptance review for the files submitted through the eSubmissions Pilot.

2. The eSubmission will serve as the only submission required; no other copies of the submission will be required.

3. The submission of Amendments and Supplements needs to be completed through the software during the eSubmissions Pilot. FDA encourages sponsor and reviewer interaction during the review process.

4. FDA will not publicly disclose participation of a sponsor in the eSubmissions Pilot, unless the sponsor consents or has already made this information public, or disclosure is required by law.

5. Participating in this eSubmissions Pilot does not guarantee clearance of a sponsor's 510(k) submission, nor is a sponsor precluded from withdrawing from the eSubmissions Pilot and pursuing a conventional 510(k)s submission and review through the current pathway.

6. Due to FDA resource issues, FDA intends to limit the eSubmissions Pilot to approximately 50 to 100 submissions. FDA may further limit the number of submissions from an individual firm as resources and eSubmissions Pilot needs allow.

7. An Extensible Markup Language (XML) Schema Definition (XSD) for the eSubmissions Pilot template was produced, and FDA intends to allow future submissions using alternative approaches to eSubmitter (e.g., via proprietary software purchased or produced by a medical device firm), as long as the submission is compliant with the XSD. If FDA commits to also receiving Regulated Product Submissions (RPS) in the future, FDA intends to expand this method of receipt to accept RPS packages. In addition, a different, more modern platform may be used for future eSubmissions other than eSubmitter.

B. Scope of eSubmissions Pilot

Voluntary participation in the eSubmissions Pilot is open to sponsors whose submissions are reviewed in ODE's Division of Cardiovascular Devices Cardiac Diagnostic Devices Branch or Peripheral Interventional Devices Branch. We encourage 510(k) sponsors of all device types, including those reviewed in other branches, to review the software interface and provide feedback via *http://www.regulations.gov* or the Division of Dockets Management (see Comments). The eSubmissions Pilot is limited to unbundled, traditional 510(k) submissions for classified devices only.[1]

C. Procedures

The following procedures have been developed to manage the CDRH eSubmissions Pilot effectively:

1. Under the eSubmissions Pilot, 510(k) submissions will be reviewed according to CDRH standard procedures.

2. eSubmission will be available for use and submission 24 hours a day and 7 days a week. However, if a 510(k) is received outside of normal business hours (Monday to Friday, 8 a.m. to 4:30 p.m. excluding Federal holidays or dates the Federal Government is shutdown), the submission receipt date will be considered the next business day.

3. Participation in the eSubmissions Pilot does not affect submission user fee obligations. If the required user fee is not paid at the time of submission, the

[1] We are not accepting third party 510(k)s or Combination Products in the eSubmissions Pilot at this time.

receipt date will be the receipt date of a complete User Fee Coversheet via eSubmission. If a User Fee Coversheet is submitted outside of normal business hours (Monday to Friday, 8 a.m. to 4:30 p.m. excluding Federal holidays or dates the Federal Government is shutdown), the User Fee Coversheet receipt date will be considered the next business day.

4. Volunteers interested in participating in the CDRH 510(k) eSubmissions Pilot should contact eSubmissions Pilot staff by email at *eSubpilot@fda.hhs.gov*. This email address should also be used to report issues and ask questions. General feedback and comments about the eSubmissions Pilot, 510(k) template, and process can be provided via *http://www.regulations.gov* or the Division of Dockets Management (see Comments).

5. Additional information on the CDRH 510(k) eSubmissions Pilot is available at *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm*.

III. Duration of the eSubmissions Pilot

FDA intends to accept requests for participation in the eSubmissions Pilot through September 30, 2014, or as resources and eSubmissions Pilot needs allow. Modifications to the CDRH 510(k) eSubmissions Pilot will be made available at *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm* to all eSubmissions Pilot participants and stakeholders.

IV. Comments

Interested persons may submit electronic comments regarding the eSubmissions Pilot for CDRH Electronic Submission of Premarket Notification Submissions to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09912 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0021]

Actavis Totowa LLC, et al.; Withdrawal of Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More Than 325 Milligrams of Acetaminophen; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 27, 2014 (79 FR 17163). The document withdrew approval of 108 abbreviated new drug applications (ANDAs) for prescription pain medications containing more than 325 milligrams (mg) of acetaminophen per dosage unit from multiple applicants, effective March 27, 2014. The document failed to withdraw approval of ANDAs 040825, 040822, and 040824, held by Ranbaxy Laboratories Inc. and Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540, and ANDA 040182, held by Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605. The holders of these applications have voluntarily requested that approval of these applications be withdrawn and have waived their opportunity for a hearing. FDA confirms the withdrawal of approval of ANDAs 040825, 040824, 040822, and 040182.

FOR FURTHER INFORMATION CONTACT: Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–5094.

SUPPLEMENTARY INFORMATION: In FR Doc. 2014–06801, appearing on page 17163, in the **Federal Register** of Thursday, March 27, 2014, the following correction is made:

On page 17166, in table 1, the following entries are added in alphabetical order by Applicant:

Application No.	Drug product(s)	Applicant or holder
ANDA 040182	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 7.5 mg/500 mg/15 milliters (mL), available in 473 mL, 118 mL, 15 mL, and 10 mL.	Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605.
ANDA 040825	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg.	Ranbaxy Laboratories Inc., 600 College Rd. East, Princeton, NJ 08540.
ANDA 040822	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg.	Do.
ANDA 040824	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg.	Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540.

Dated: April 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09898 Filed 4–30–14; 8:45 am]

BILLING CODE 4160–01–P