introduction of new products or at inspection). The license holder is responsible for reporting these changes to FDA (§ 601.12).

2. Notification of Results of Tests and Investigations Regarding or Possibly Impacting the Product

In the guidance, we recommend the following for contract manufacturing arrangements:

- The contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product; and
- The license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.

3. Notification of Products Manufactured in a Contract Facility

In the guidance, we recommend for contract manufacturing arrangements that a license manufacturer cross reference a contract manufacturing facility's Master Files only in circumstances involving certain proprietary information of the contract manufacturer, such as a list of all products manufactured in a contract facility. In this situation, the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

4. Standard Operating Procedures

In the guidance, we remind the license manufacture that the license manufacturer assumes responsibility for compliance with the applicable product and establishment standards (21 CFR 600.3(t)). Therefore, if the license manufacturer enters into an agreement with a contract manufacturing facility, the license manufacturer must ensure that the facility complies with the applicable standards. An agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance. These procedures may include, but are not limited to, review of records and manufacturing deviations and defects, and periodic audits.

For shared manufacturing arrangements, each manufacturer must submit a separate biologics license application (BLA) describing the manufacturing facilities and operations applicable to the preparation of that manufacturer's biological substance or product (§ 601.2(a)). In the guidance, we state that we expect the manufacturer that prepares (or is responsible for the preparation of) the product in final form for commercial distribution to assume primary responsibility for providing data demonstrating the safety, purity, and potency of the final product. We also state that we expect the licensed finished product manufacturer to be primarily responsible for any postapproval obligations, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4) and adverse experience reporting. We recommend that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain information in these areas.

Description of Respondents: The recordkeeping and reporting recommendations described in this document affect the participating licensed manufacturer(s), final product manufacturer(s), and contract manufacturer(s) associated with cooperative manufacturing arrangements.

Burden Estimate: We believe that the information collection provisions in the guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practices. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

The guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, and 807, 809, and 820 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820). The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB control number 0910–0116; § 610.2 has been approved under OMB control number 0910–0206; §§ 600.12(e) and 600.80 have been approved under OMB control number 0910–0308; §§ 601.2(a), 601.12, 610.60 through 610.65, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), (c) through (g), (i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB control number 0910–0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB control number 0910–0437; and §§ 600.14 and 606.171 have been approved under OMB control number 0910–0458. The current good manufacturing practice regulations for finished pharmaceuticals (part 211) have been approved under OMB control number 0910–0139; §§ 820.181 and 820.184 have been approved under OMB control number 0910–0073; the establishment registration regulations (parts 207, 607, and 807) have been approved under OMB control numbers 0910–0045, 0910–0052, and 0910–0625; and the labeling regulations (parts 201, 801, and 809) have been approved under OMB control numbers 0910–0537, 0910–0572, and 0910–0485.

Dated: July 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15810 Filed 7–3–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0587]

Guidance for Industry on Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention.'' The purpose of the guidance is to assist sponsors in the development of drugs for the treatment or prevention of neglected tropical diseases (NTDs). This guidance represents the FDA's current thinking regarding drug development for the treatment or prevention of NTDs, including clinical trial designs and internal review standards to support approval of drugs. This guidance finalizes the draft guidance issued August 24, 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your

requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment or prevention of NTDs as defined in section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)).

NTDs are infectious diseases that are generally rare or absent in developed countries, but are often widespread in developing countries. The availability of new drugs that are safe and effective for treatment or prevention of NTDs could provide public health benefit for overall global health.

This guidance addresses general issues in drug development and implementation of clinical trials for NTDs. FDA will review and comment on drug development plans and will review new drug applications or biologics license applications for new drugs for NTDs, regardless of where the clinical development program takes place. Specifically, the guidance provides a general overview of nonclinical development considerations, as well as clinical development considerations and regulatory paradigms. Other activities in the Center for Drug Evaluation and Research that pertain to NTDs are summarized in the guidance. Listings of guidance documents that are most relevant to drug development for NTDs are included in the guidance.

This guidance finalizes the draft guidance issued August 24, 2011. Comments on the draft guidance were considered while finalizing this guidance. Specifically, changes from the draft guidance include descriptions of new regulatory designations (Qualified Infectious Disease Product; Breakthrough Therapy).

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 developing drugs for the treatment or prevention of neglected tropical diseases of the developing world. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 and 21 CFR part 314 have been approved under OMB control numbers 0910–0014 and 0910–0001.

III. Comments

Interested persons may submit either electronic 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15801 Filed 7–3–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 23, 2014, from 8 a.m. to 5:30 p.m.

Location: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993–0002, 301–796–0885, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act for: AFINITOR DISPERZ (everolimus); Berlin Heart EXCOR® Pediatric Ventricular Assist Device; CONTEGRA® Pulmonary Valved Conduit; DYMISTA (azelastine hydrochloride; fluticasone propionate); Elana Surgical Kit; ENTERRA Therapy System; LEVAQUIN (levofloxacin); LEXIVA (fosamprenavir calcium); QNASL (beclomethasone diproprionate), Medtronic Melody® Transcatheter Pulmonary Valve; MENHIBRIX (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine); SINGULAIR (montelukast sodium); TREANDA (bendamustine hydrochloride); VERAMYST (fluticasone furoate); VIREAD (tenofovirdisoproxil fumarate); and VOLUVEN (6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection).

FDA intends to make background material available to the public no later