revenue in 2013. Virbac Corp. is well suited to acquire the Sentinel products because of its current presence in the companion animal health business, and because it already has experience with canine heartworm products. Although Virbac currently sells canine heartworm products, their sales are relatively small and, because they do not contain an active ingredient to treat fleas, their competitive interaction with the Sentinel products is limited.

The Order requires Eli Lilly to divest all of its respective rights and interests in the Sentinel products no later than ten days after the consummation of the Proposed Acquisition or on the date on which the Order becomes final, whichever is earlier. The divestiture includes all regulatory approvals, brand names, marketing materials, and confidential business information, including customer information, related to the Sentinel products, and other assets associated with producing, marketing and selling the Sentinel products. To ensure the divestiture is successful, the Order requires Eli Lilly and Novartis to secure all third-party consents and waivers required to permit Virbac to conduct business with the Sentinel products. The Order also requires Eli Lilly to divest supply chain assets related to the Sentinel products. These assets include certain rights and intellectual property for the active pharmaceutical ingredients in the Sentinel products. Additionally, Eli Lilly and Virbac must complete a technical transfer of manufacturing from Novartis to Virbac. The Order calls for an interim supply agreement of the Sentinel products for up to four years while Eli Lilly and Virbac complete the technical transfer.

The Commission has agreed to appoint an Interim Monitor to ensure that Eli Lilly and Novartis comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Virbac.

The Commission's goal in evaluating possible purchasers of divested rights and assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Virbac is not an acceptable acquirer of the divested rights and assets, or that the manner of the divestitures is not acceptable, the parties must unwind the sale of rights and assets to Virbac and divest them to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the rights and assets if the parties fail to divest them as required.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Janice Podoll Frankle,

Acting Secretary.

[FR Doc. 2014–30686 Filed 12–30–14; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2254]

The Drug Supply Chain Security Act Implementation: Product Tracing Requirements—Compliance Policy; Guidance for Industry; 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 ''DSCSA Implementation: Product Tracing Requirements—Compliance Policy.'' This guidance announces FDA's intention with regard to enforcement of certain product tracing requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Supply Chain Security Act (DSCSA). FDA does not intend to enforce these requirements against manufacturers, wholesale distributors, and repackagers who do not, prior to May 1, 2015, provide or capture the transaction information, transaction history, and transaction statement required by the FD&C Act (product tracing information) for transaction of certain human, finished prescription drugs that are covered in the statute.

DATES: Effective December 31, 2014. For information about enforcement dates, please see the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: All responses to this notice should be identified with Docket No. FDA–2014–D–2254 and directed to the office listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''DSCSA Implementation: Product Tracing Requirements—Compliance Policy.'' This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance has been implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate. (§ 10.115(g)(2)). This guidance document provides information pertaining to statutory requirements that will take effect on January 1, 2015, regarding the provisions to provide and capture product tracing information under section 582(b)(1), (c)(1), and (e)(1) of the FD&C Act (21 U.S.C. 360eee–1(b)(1), (c)(1), and (e)(1)). It is important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices. (§ 10.115(g)(3)).

On November 27, 2013, the DSCSA (Title II of Pub. L. 113–54) was signed into law. Section 202 of the DSCSA added sections 581 and 582 to the FD&C Act, which set forth new definitions and requirements for the tracing of products through the pharmaceutical distribution supply chain. Starting in 2015, trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) will be required under section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act, to exchange product tracing information when engaging in transactions involving certain prescription drugs. Manufacturers, wholesale distributors, and repackagers must meet these requirements by January 1, 2015; dispensers must meet these requirements by July 1, 2015.

Although the product tracing requirements under section 582(b), (c), and (e) of the FD&C Act go into effect for manufacturers, wholesale distributors, and repackagers on January 1, 2015, some trading partners have expressed concern that unforeseen complications with the exchange of the required information may result in disruptions in the pharmaceutical supply chain, and ultimately could impact patients' access to needed prescription drugs. FDA recognizes that some manufacturers, wholesale distributors, and repackagers may need time beyond January 1, 2015, to work

with trading partners to ensure that all the proper product tracing information is provided and captured. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA does not intend to take action against trading partners who do not, prior to May 1, 2015, provide or capture the product tracing information required by section 582(b)(1), (c)(1), and (e)(1) of the FD&C Act. This compliance policy is limited to the requirements that trading partners provide and capture product tracing information; it does not extend to other requirements in section 582 of the FD&C Act, such as verification of suspect and illegitimate products (including quarantine, investigation, notification, and recordkeeping) or the requirement to engage only in transactions with authorized trading partners.

II. Comments

This guidance is for immediate implementation. FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments 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. You should identify all comments with Docket No. FDA–2014–D–2254.

III. Electronic Access

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

Dated: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30608 Filed 12–30–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIDA).

SUMMARY: National Institute on Drug Abuse (NIDA), National Institutes of Health, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et. seq.). This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

To submit comments and for further information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Genevieve deAlmeida, Ph.D., Health Research Evaluator, Office of Science Policy and Communications, National Institute on Drug Abuse, NIH, 6001 Executive Boulevard, Bethesda, MD, Bethesda, MD 20892–9557, or call non-toll-free number (301) 594–6802, or Email your request, including your address to: *dealmeig@nida.nih.gov* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIDA), 0925–0655, Expiration Date 3/31/2015, EXTENSION, National Institute on Drug Abuse (NIDA).

Need and Use of Information Collection: The information collected under this clearance will be qualitative customer and stakeholder feedback information—their perceptions, experiences and expectations of services, issues with service, to focus attention on areas where communication, training or changes in operations might improve delivery of products or services. The information will be useful and will allow for collaborative and actionable communications between the Agency and its customers and stakeholders, and will contribute directly to improving the programs and management of them.

The information will not yield data that can be generalized to the overall population. The information may also be formative for the purpose of developing a concept for a new service program or dissemination program. The collections may still be eligible for submission for other generic mechanisms designed to yield quantitative results.

The primary objectives are to obtain feedback on programs from customers and stakeholders, that would help make positive changes to the programs, or to assist in developing a new program or dissemination initiative, or to test medical tools and devices for usability, feasibility, and pilot testing of survey questionnaires for understandability. Data collection methods to be used in these studies include web-based and mailed surveys, focus groups, interviews with small groups, ad hoc collections at Conferences. The findings will provide valuable information to assist in improving programs that serve the public, and in developing good tools and devices to serve the public. OMB approval is requested for 3 years.

NIDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses