DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 16

[Docket No. FDA–2013–N–0365]

Administrative Detention of Drugs Intended for Human or Animal Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation to implement administrative detention authority with respect to drugs intended for human or animal use as authorized by amendments made to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by the Food and Drug Administration Safety and Innovation Act (FDASIA). Once the applicable regulation is finalized, FDA's administrative detention authority with respect to drugs will allow FDA to better protect the integrity of the drug supply chain. Specifically, FDA will be able to administratively detain drugs encountered during an inspection that an officer or employee conducting an inspection has reason to believe are adulterated or misbranded. This authority is intended to protect the public by preventing distribution or subsequent use of drugs encountered during inspections that are believed to be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate.

DATES: Submit either electronic or written comments on the proposed rule by September 13, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0365, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier* (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0365. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charlotte Hinkle, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4345, Silver Spring, MD 20993–0002, 301–796–5300, *FDASIA ImplementationORA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

FDA's administrative detention authority with respect to drugs intended for human or animal use will allow FDA to better protect the integrity of the drug supply chain. Specifically, administrative detention is intended to protect the public by preventing distribution or subsequent use of drugs encountered during inspections that may be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. FDA already has the authority to administratively detain devices, tobacco, and foods that FDA has reason to believe are adulterated or misbranded.

FDA is issuing this proposed rule under section 304(g) of the FD&C Act, as amended by section 709 of FDASIA, and section 701 of the FD&C Act (21 U.S.C. 334(g) and 371). Section 304(g) also authorizes FDA to administratively detain devices and tobacco products.

Summary of the Major Provisions

This notice contains a proposed rule regarding the administrative detention of drugs. FDA proposes to amend parts 1 and 16 (21 CFR parts 1 and 16) to create an implementing rule for this authority. The proposed changes set forth the procedures for detention of drugs believed to be adulterated or misbranded and amend the scope of FDA's part 16 regulatory hearing procedures to include the administrative detention of drugs.

Costs and Benefits

The primary public health benefits from adoption of the proposed rule would be the value of the illnesses or deaths prevented because the Agency administratively detained a drug it has reason to believe is adulterated or misbranded; this benefit occurs only if the drug would not have been prevented from entering the market using one of the Agency's other enforcement tools. The estimated primary costs to FDA include marking or labeling the detained product and costs associated with appeals of detention orders. The Agency estimates the net annual social costs to be between $0 and $591,480.

I. Background

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA, Pub. L. 112–144) into law. Title VII of FDASIA provides FDA with important new authorities to help it better protect the integrity of the drug supply chain. One of those new authorities is section 709, which amends section 304(g) of the FD&C Act (21 U.S.C. 334(g)) to provide FDA with administrative detention authority with respect to drugs. Section 304(g) of the FD&C Act, as amended by FDASIA, provides FDA the same authority to detain drugs that section 304(g) already provides FDA with respect to devices and tobacco products. Once implementing regulations with respect to drugs are finalized, the amendments to section 304(g) of the FD&C Act will take effect, allowing FDA to administratively detain drugs that an officer or employee conducting an inspection under section 704 of the FD&C Act has reason to believe are adulterated or misbranded.

FDA's administrative detention authority with respect to drugs will allow FDA to drive safety and quality through the drug supply chain. Use of this authority is intended to protect the public by preventing distribution or subsequent use of drugs encountered during inspections that may be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate.

Section 709 of FDASIA requires the Secretary to ''consult with stakeholders, including manufacturers of drugs'' before issuing implementing regulations. Section 709 of FDASIA also requires FDA to issue a notice of proposed rulemaking that includes the proposed regulation and provides a period of at least 60 days for comments on the proposed regulation. Finally,

section 709 of FDASIA states that FDA must ''publish the final regulation not less than 30 days before the regulation's effective date'' and states that FDA must issue regulations no later than 2 years after enactment of FDASIA.

On April 9, 2013, FDA published a document in the **Federal Register** that opened a 30-day public docket to solicit input from all relevant stakeholders regarding FDA's issuance of regulations for the administrative detention of drugs (78 FR 21085). The docket was intended to ensure that stakeholders had an opportunity to provide comments before FDA issued proposed regulations on administrative detention with respect to drugs and to ensure that such information submitted to FDA was available to all interested persons in a timely fashion.

The 30-day public docket closed on May 9, 2013. FDA received one responsive, non-substantive comment. The Agency did not consider nonresponsive comments in developing this proposed rule. FDA notes that this announcement regarding the proposed rule also solicits input from all relevant stakeholders before FDA issues final regulations to implement its administrative detention authority with respect to drugs. FDA modeled the proposed regulations for the administrative detention of drugs on the existing regulations covering administrative detention of devices (see 21 CFR 800.55). FDA did so because of identical statutory authority underlying the regulations (21 U.S.C. 334(g)).

II. Proposed Changes to Current Regulations

A. Proposed Revisions to Part 1

FDA proposes to amend part 1 (21 CFR part 1) to create an implementing regulation for the administrative detention of drugs. The proposed amendment to part 1 consists of one section, § 1.501, under a new subpart, which is titled ''Subpart L—Administrative Detention of Drugs Intended for Human or Animal Use.'' Proposed § 1.501 sets forth the procedures for the administrative detention of drugs encountered during an inspection that are believed to be adulterated or misbranded. The new regulation is closely modeled on the current regulation for the administrative detention of devices (21 CFR 800.55). There are minor differences from the device regulation, including updates to statutory references to refer to drugs instead of devices and changes to language to conform to current **Federal Register** requirements.

B. Proposed Revisions to Part 16

The proposed amendment to part 16 is a technical change. This change amends a statement in § 16.1 so that the scope of part 16 regulatory hearing procedures will also include administrative detention authority with respect to drugs.

III. Effective Date

FDA intends that the effective date of the new requirements will be 30 days after publication of a final rule in the **Federal Register**. Section 709 of FDASIA states that FDA's new authority under section 304(g) of the FD&C Act shall not take effect until FDA issues a final regulation, and section 709 requires FDA to ''publish the final regulation not less than 30 days before the regulation's effective date.'' Finally, section 709 of FDASIA requires that no later than 2 years after enactment of FDASIA, regulations to implement administrative detention authority with respect to drugs must be issued. Therefore, FDA intends to issue the final rule for administrative detention authority with respect to drugs by July 9, 2014, with an effective date for the final rule no later than August 8, 2014.

IV. Legal Authority

FDA is issuing this proposed rule under sections 304(g) and 701 of the FD&C Act and section 709 of FDASIA. Section 709 of FDASIA provides FDA authority to issue regulations regarding administrative detention authority with respect to drugs. Section 304(g) of the FD&C Act includes FDA's administrative detention authority with respect to drugs. The proposed rule is necessary for efficient enforcement of the FD&C Act.

V. Analysis of Impacts (Summary of the Initial Regulatory Impact Analysis)

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule would not be an economically significant regulatory action as defined by Executive Order 12866.

If a rule has a significant economic impact on a substantial number of small businesses, the Regulatory Flexibility Act requires Agencies to analyze regulatory alternatives that would minimize any significant impact of a rule on small entities. FDA has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The primary public health benefits from adoption of the proposed rule would be the value of the illnesses or deaths prevented because the Agency administratively detained a drug it has reason to believe is adulterated or misbranded; this benefit occurs only if the drug would not have been prevented from entering the market using one of the Agency's other enforcement tools. There may also be benefits from deterrence if administrative detention increases the likelihood misbranded or adulterated products will not be marketed in the future.

The estimated primary costs to FDA include marking or labeling the detained product and costs associated with appeals of the detention orders. However, other costs, such as loss in market value of a detained drug, may be incurred if FDA revokes the detention order on appeal. Given the history of administrative detention use with medical devices and foods, the likelihood is low of FDA issuing a detention order that is later revoked on appeal.

We estimate the annual costs using a range of 0 to 20 administrative detentions performed each year. The Agency estimates the net annual social costs to be between $0 and $591,480. The present discounted value over 20 years would be in the range of $0 to $8,799,729 at a 3 percent discount rate and in the range of $0 to $6,266,148 at a 7 percent discount rate.

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this proposed rule would not have a significant economic impact on a substantial number of small entities. This analysis, together with other relevant sections of this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

VI. Paperwork Reduction Act of 1995

FDA concludes that the requirements proposed in this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)(ii)).

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. 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*.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1 and 16 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Add subpart L, consisting of § 1.501, to read as follows:

Subpart L—Administrative Detention of Drugs Intended for Human or Animal Use

§ 1.501 Administrative detention of drugs.

(a) *General.* This section sets forth the procedures for detention of drugs believed to be adulterated or misbranded. Administrative detention is intended to protect the public by preventing distribution or use of drugs encountered during inspections that may be adulterated or misbranded, until the Food and Drug Administration (FDA) has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. Drugs that FDA orders detained may not be used, moved, altered, or tampered with in any manner by any person during the detention period, except as authorized under paragraph (h) of this section, until FDA terminates the detention order under paragraph (j) of this section, or the detention period expires, whichever occurs first.

(b) *Criteria for ordering detention.* Administrative detention of drugs may be ordered in accordance with this section when an authorized FDA representative, during an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act, has reason to believe that a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act, is adulterated or misbranded.

(c) *Detention period.* The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA District Director in whose district the drugs are located determines that a greater period is required to seize the drugs, to institute injunction proceedings, or to evaluate the need for legal action, in which case the District Director may authorize detention for 10 additional calendar days. The additional 10-calendar-day detention period may be ordered at the time the detention order is issued or at any time thereafter. The entire detention period may not exceed 30 calendar days, except when the detention period is extended under paragraph (g)(6) of this section. An authorized FDA representative may, in accordance with paragraph (j) of this section, terminate a detention before the expiration of the detention period.

(d) *Issuance of detention order.* (1) The detention order must be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the drugs are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the drugs are located. If the owner or the user of the drugs is different from the owner, operator, or agent in charge of the place where the drugs are detained, a copy of the detention order must be provided to the owner or user of the drugs if the owner's or user's identity can be readily determined.

(2) If detention of drugs in a vehicle or other carrier is ordered, a copy of the detention order must be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined.

(3) The detention order must include the following information:

(i) A statement that the drugs identified in the order are detained for the period shown;

(ii) A brief, general statement of the reasons for the detention;

(iii) The location of the drugs;

(iv) A statement that these drugs are not to be used, moved, altered, or tampered with in any manner during that period, except as permitted under paragraph (h) of this section, without the written permission of an authorized FDA representative;

(v) Identification of the detained drugs;

(vi) The detention order number;

(vii) The date and hour of the detention order;

(viii) The period of the detention;

(ix) The text of section 304(g) of the Federal Food, Drug, and Cosmetic Act and paragraphs (g)(1) and (g)(2) of this section;

(x) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in paragraph (g)(3) of this section; and

(xi) The location and telephone number of the FDA district office and the name of the FDA District Director.

(e) *Approval of detention order.* A detention order, before issuance, must be approved by the FDA District Director in whose district the drugs are located. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum within FDA as soon as possible.

(f) *Labeling or marking a detained drug.* An FDA representative issuing a detention order under paragraph (d) of this section must label or mark the drugs with official FDA tags that include the following information:

(1) A statement that the drugs are detained by the U.S. Government in accordance with section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)).

(2) A statement that the drugs must not be used, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative, except as authorized in paragraph (h) of this section.

(3) A statement that the violation of a detention order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 303 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 333).

(4) The detention order number, the date and hour of the detention order, the detention period, and the name of the FDA representative who issued the detention order.

(g) *Appeal of a detention order.* (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA District Director in whose district the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized.

(3) Any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that:

(i) The detention order under paragraph (d) of this section, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter;

(ii) A request for a hearing under this section should be addressed to the FDA District Director;

(iii) The last sentence of § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this section;

(iv) Paragraph (g)(4) of this section, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., regional food and drug directors, who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also must decide the appeal, must be a regional food and drug director (i.e., a director of an FDA regional office listed in part 5, subpart M of this chapter) who is permitted by § 16.42(a) of this chapter to preside over the hearing.

(5) If the appellant requests a regulatory hearing and requests that the hearing be held within 5 working days after the appeal is filed, the presiding officer must, within 5 working days, hold the hearing and render a decision affirming or revoking the detention.

(6) If the appellant requests a regulatory hearing and requests that the hearing be held at a date later than within 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer must hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer must decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing. The detention period extends to the date of the decision even if the 5-working-day period for making the decision extends beyond the otherwise applicable 20-calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals the detention order but does not request a regulatory hearing, the presiding officer must render a decision on the appeal affirming or revoking the detention within 5 working days after the filing of the appeal.

(8) If the presiding officer affirms a detention order, the drugs continue to be detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(9) If the presiding officer revokes a detention order, FDA must terminate the detention under paragraph (j) of this section.

(h)(1) *Movement of detained drugs.* Except as provided in this paragraph, no person may move detained drugs within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained drugs are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the drugs are moved for this purpose, the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible district office official, of the movement of the drugs. As soon as the drugs are put in final form, they must be segregated from other drugs, and the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible district office official, of their new location. The drugs put in final form must not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible district office official, may approve, in writing, the movement of detained drugs for any of the following purposes:

(i) To prevent interference with an establishment's operations or harm to the drugs;

(ii) To destroy the drugs;

(iii) To bring the drugs into compliance;

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible district office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained drugs under paragraph (h)(3) of this section, the detained drugs must remain segregated from other drugs and the person responsible for their movement must immediately orally notify the official who approved the movement of the drugs, or another responsible FDA district office official, of the new location of the detained drugs.

(5) Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of drugs under this paragraph, the required tags must accompany the drugs during and after movement and must remain with the drugs until FDA terminates the detention or the detention period expires, whichever occurs first.

(i) *Actions involving adulterated or misbranded drugs.* If FDA determines that the detained drugs, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal action against the drugs or the responsible individuals, or both, or request that the drugs be destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act under FDA's supervision.

(j) *Detention termination.* If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice releasing the drugs to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(k) *Recordkeeping requirements.* (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent in charge of any factory, warehouse, other establishment, or consulting laboratory where detained drugs are manufactured, processed, packed, or held, must have, or establish, and maintain adequate records relating to how the detained drugs may have become adulterated or misbranded, records on any distribution of the drugs before and after the detention period, records on the correlation of any in-process detained drugs that are put in final form under paragraph (h) of this section to the completed drugs, records of any changes in, or processing of, the drugs permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph must be provided to the FDA on request for review and copying. Any FDA request for access to records required under this paragraph must be made at a reasonable time, must state the reason or purpose for the request, and must identify to the fullest extent practicable the information or type of information sought in the records to which access is requested.

(2) Records required under this paragraph must be maintained for a maximum period of 2 years after the issuance of the detention order or for such other shorter period as FDA directs. When FDA terminates the detention or when the detention period expires, whichever occurs first, FDA will advise all persons required under this paragraph to keep records concerning that detention whether further recordkeeping is required for the remainder of the 2-year, or shorter, period. FDA ordinarily will not require further recordkeeping if the Agency determines that the drugs are not adulterated or misbranded or that recordkeeping is not necessary to protect the public health, unless the records are required under other regulations in this chapter (e.g., the good manufacturing practice regulation in part 211 of this chapter).

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 3. The authority citation for 21 CFR part 16 is revised to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467F, 679, 821, 1034; 42 U.S.C. 201–262, 263b, 364.

■ 4. Revise the first sentence of § 16.1 paragraph (b)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices and drugs (see §§ 800.55(g) and 1.501(g) of this chapter). * * *

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16843 Filed 7–12–13; 8:45 am]

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