Dated: September 21, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0279]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by October 31, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@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.

Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements—21 CFR Part 203—(OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the PRA (44 U.S.C. 3501–3520) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 100–293). PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against U.S. manufacturers and had provided the cover for the importation of foreign counterfeit drugs.

Congress also determined that the system of providing drug samples to physicians through manufacturers' representatives had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

The bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail also helped to fuel the diversion market and was an unfair form of competition to wholesalers and retailers who had to pay otherwise prevailing market prices.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements:

TABLE 1—REPORTING REQUIREMENTS

21 CFR Section	Requirement
203.11	Applications for reimportation to provide emergency medical care.
203.30(a)(1) and (b)	Drug sample requests (drug samples distributed by mail or common carrier).
203.30(a)(3), (a)(4), and (c)	Drug sample receipts (receipts for drug samples distributed by mail or common carrier).
203.31(a)(1) and (b)	Drug sample requests (drug samples distributed by means other than the mail or a common carrier).
203.31(a)(3), (a)(4), and (c)	Drug sample receipts (drug samples distributed by means other than the mail or a common carrier).
203.37(a)	Investigation of falsification of drug sample records.
203.37(b)	Investigation of a significant loss or known theft of drug samples.
203.37(c)	Notification that a representative has been convicted of certain offenses involving drug samples.
203.37(d)	Notification of the individual responsible for responding to a request for information about drug samples.
203.39(g)	Preparation by a charitable institution of a reconciliation report for donated drug samples.

TABLE 2—RECORDKEEPING REQUIREMENTS

21 CFR Section	Requirement
203.23(a) and (b)	Credit memo for returned drugs.
203.23(c)	Documentation of proper storage, handling, and shipping conditions for returned drugs.
203.30(a)(2) and 203.31(a)(2)	Verification that a practitioner requesting a drug sample is licensed or authorized by the appropriate State authority to prescribe the product.
203.31(d)(1) and (d)(2)	Contents of the inventory record and reconciliation report required for drug samples distributed by representatives.

TABLE 2—RECORDKEEPING REQUIREMENTS—Continued

21 CFR Section	Requirement
203.31(d)(4)	Investigation of apparent discrepancies and significant losses revealed through the reconciliation report.
203.31(e)	Lists of manufacturers' and distributors' representatives.
203.34	Written policies and procedures describing administrative systems.
203.37(a)	Report of investigation of falsification of drug sample records.
203.37(b)	Report of investigation of significant loss or known theft of drug samples.
203.38(b)	Records of drug sample distribution identifying lot or control numbers of samples distributed. (The information collection in 21 CFR 203.38(b) is already approved under OMB control number 0910–0139).
203.39(d)	Records of drug samples destroyed or returned by a charitable institution.
203.39(e)	Record of drug samples donated to a charitable institution.
203.39(f)	Records of donation and distribution or other disposition of donated drug samples.
203.39(g)	Inventory and reconciliation of drug samples donated to charitable institutions.
203.50(a)	Drug origin statement.
203.50(b)	Retention of drug origin statement for 3 years.
203.50(d)	List of authorized distributors of record.

The reporting and recordkeeping requirements are intended to help achieve the following goals: (1) To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care; (2) to ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample; (3) to limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other health care entities at the request of a licensed or authorized practitioner; (4) to require licensed or authorized practitioners to request prescription drug samples in writing; (5) to mandate storage, handling, and recordkeeping requirements for prescription drug samples; (6) to prohibit, with certain exceptions, the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or other health care entities, or which were donated or supplied at a reduced price to a charitable organization; (7) to require unauthorized wholesale distributors to provide, prior to the wholesale distribution of a prescription drug to another wholesale distributor or retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

In the **Federal Register** of June 6, 2011 (76 FR 32362), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment. The comment did not pertain to the information collection discussed in the June 2011 **Federal Register** notice, but commended the use of electronic and automated health information solutions to reduce costs and improve health care efficiency.

FDA Response: There were no issues raised in the comment to be resolved.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response (in hours)	Total hours
203.11	1	1	1	.5	.5
203.30(a)(1) and (b)	61,961	12	743,532	.06	44,612
203.30(a)(3), (a)(4), and (c)	61,961	12	743,532	.06	44,612
203.31(a)(1) and (b)	232,355	135	31,367,925	.04	1,254,717
203.31(a)(3), (a)(4), and (c)	232,355	135	31,367,925	.03	941,038
203.37(a)	50	4	200	.25	50
203.37(b)	50	40	2,000	.25	500
203.37(c)	1	1	1	1	1
203.37(d)	50	1	50	.08	4
203.39(g)	1	1	1	1	1
Total					2,285,535.5

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
203.31(d)(1) and (d)(2)	2,208	1	2,208	40	88,320
203.31(d)(4)	442	1	442	24	10,608
203.31(e)	2,208	1	2,208	1	2,208
203.34	90	1	90	40	3,600
203.37(a)	50	4	200	6	1,200
203.37(b)	50	40	2000	6	1,200
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8	25,768
203.39(g)	3,221	1	3,221	8	25,768
203.50(a)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2	1,382
Total					332,769

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

Dated: September 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25117 Filed 9–28–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0023]

Guidance for Industry on Target Animal Safety and Effectiveness Protocol Development and Submission; 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 (#215) entitled ''Target Animal Safety and Effectiveness Protocol Development and Submission.'' The purpose of this document is to provide sponsors guidance in preparation of study protocols for review by the Center for Veterinary Medicine, Office of New Animal Drug Evaluation. The recommendations included in this guidance are intended to reduce the time to protocol concurrence.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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: Angela Clarke, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8318; *e-mail: angela.clarke@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 3, 2011 (76 FR 6143), FDA published the notice of availability for a draft guidance entitled ''Target Animal Safety and Effectiveness Protocol Development and Submission,'' giving interested persons until April 19, 2011, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. Changes include editorial revisions to improve clarity regarding how and when data collection forms and standard operating procedures should be included with the protocol submission. The guidance announced in this notice finalizes the draft guidance dated February 2, 2011.

II. Significance of Guidance

This level 1 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 topic. 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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 this guidance have been approved under OMB control no. 0910–0032.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*