TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Contact lens cleaning solution labeling—800.10(a)(3) and 800.12(c)	17	8	136	1	136
Liquid ophthalmic preparation labeling—800.10(b)(2)	17	8	136	1	136
Manufacturer, packer, or distributor information—801.1	13,780	7	96,460	1	96,460
Adequate directions for use—801.5	6,657	6	39,942	22.35	892,704
Statement of identity—801.61	6,657	6	39,942	1	39,942
Declaration of net quantity of contents—801.62	6,657	6	39,942	1	39,942
Prescription device labeling—801.109	7,558	6	45,348	17.77	805,834
Retail exemption for prescription devices—801.110	30,000	667	20,010,000	0.25	5,002,500
Processing, labeling, or repacking; non-sterile devices—801.150(e)	377	34	12,818	4	51,272
Labeling of articles intended for lay use in the repairing and/or refitting of dentures—801.405(b)(1)	31	1	31	4	124
Dentures; information regarding temporary and emergency use—801.405(c)	31	1	31	4	124
Labeling requirements for hearing aids—801.420(c)(1)	86	12	1,032	40	41,280
Technical data for hearing aids—801.420(c)(4)	86	12	1,032	80	82,560
Hearing aids, opportunity to review user instructional brochure—801.421(b)	10,000	160	1,600,000	0.30	480,000
Hearing aids, availability of user instructional brochure—801.421(c)	10,000	5	50,000	0.17	8,500
User labeling for menstrual tampons—801.430(d)	22	8	176	2	352
Menstrual tampons, ranges of absorbency—801.430(e)(2)	22	8	176	2	352
User labeling for latex condoms—801.435(b), (c), and (h)	63	6	378	100	37,800
Labeling for IVDs—809.10(a) and (b)	1,700	6	10,200	80	816,000
Labeling for general purpose laboratory reagents—809.10(d)(1)	300	2	600	40	24,000
Labeling for analyte specific reagents—809.10(e)	300	25	7,500	1	7,500
Labeling for OTC test sample collection systems for drugs of abuse testing—809.10(f)	20	1	20	100	2,000
Advertising and promotional materials for ASRs—809.30(d)	300	25	7,500	1	7,500
Labeling of sunlamp products—1040.20(d)	30	1	30	10	300
Total					8,437,318

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

Dated: January 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01668 Filed 1–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0509]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

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.

DATES: Fax written comments on the collection of information by March 2, 2015.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0566. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@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.

Appeals of Science-Based Decisions Above the Division Level at CVM—21 CFR 10.75 (OMB Control Number 0910–0566—Revision)

Respondents: Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

The Center for Veterinary Medicine's (CVM's) guidance for industry #79 entitled ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine,'' describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the

guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

In the **Federal Register** of November 6, 2014 (79 FR 65976), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but it did not respond to any of the four collection of information topics solicited in the notice and therefore is not discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.75	2	4	8	10	80

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

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method, then CVM recommends that the applicant follow the procedure in guidance for industry #79. Of the two respondents who were advised on the procedure during the past 3 years, one has not followed up to initiate it and the other is working with the review team/group to resolve the issue(s). Therefore, this estimated annual reporting burden is based on CVM's previous experience in handling formal appeals for scientific disputes.

Dated: January 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01669 Filed 1–28–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1069]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Blood Establishment Registration and Product Listing

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.

DATES: Fax written comments on the collection of information by March 2, 2015.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0052. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR Part 607 (OMB Control Number 0910–0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register his or her name, place of business, and all such establishments with the Secretary of Health and Human Services on or before December 31 of each year. He or she must also submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a), in brief, requires owners or operators of certain establishments that engage in the manufacture of blood products to register and to submit a list of every blood product in commercial distribution.

Section 607.21, in brief, requires the owners or operators of establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a list of every blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation for which a license is required, registration must follow within 5 days after the submission of a biologics license application. In addition, owners or operators of all establishments so engaged must register annually between November 15 and December 31 and update their blood product listing every June and December.

Section 607.22 requires the use of Form FDA 2830, Blood Establishment Registration and Product Listing, for initial registration, for subsequent annual registration, and for blood product listing information.

Section 607.25 sets forth the information required for establishment registration and blood product listing.

Section 607.26, in brief, requires certain changes to be submitted on FDA Form 2830 as an amendment to