

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Respondents	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews					
Physicians	6	1	6	1	6
Advanced practice nurses (NPs) and registered nurses	9	1	9	1	9
Medical technicians	9	1	9	1	9
Subtotal	24	1	24	1	24
Survey					
Physicians	120	1	120	.5	60
Advanced practice nurses (NPs) and registered nurses	240	1	240	.5	120
Medical technicians	240	1	240	.5	120
Total					324

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

Dated: October 26, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0554]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

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 December 1, 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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0363. 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.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910-0363)—(Extension)

With the passage of the Animal Drug Availability Act of 1996 (ADAA) (Pub. L. 104-250), the Congress enacted legislation establishing a new class of

restricted feed use drugs, veterinary feed directive (VFD) drugs, which may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6) is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and records must be maintained of the distribution of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

In the **Federal Register** of August 3, 2011(76 FR 46818), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments that pertained to the information collection burden estimates.

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
558.6(a)(3) through (a)(5)	15,000	25	375,000	.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	.25	75
558.6(d)(1)(iv)	20	1	20	.25	5
558.6(d)(2)	1,000	5	5,000	.25	1,250
514.1(b)(9)	1	1	1	3	3

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total	95,083

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR section	Number of Record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
Total	25,051

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

The estimate of the times required for record preparation and maintenance is based on Agency communication with industry and Agency records and experience.

Dated: October 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0770]

Cosmetic Microbiological Safety Issues; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments and opening of a docket.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled “Cosmetic Microbiological Safety Issues.” The purpose of the public meeting is to provide stakeholders an opportunity to present information regarding cosmetic microbiological safety and to suggest areas for the possible development of FDA guidance documents. FDA is seeking information regarding microbiological testing of cosmetics; types of preservative systems and how to test their efficacy; the identity and prevalence of microorganisms, including antibiotic-resistant strains, that pose specific health risks in finished products; routes of exposure to microorganisms and the corresponding infective doses; product and packaging

characteristics that affect microbial growth and risk of infection; particular subpopulations that may be at greater risk of infection when using different cosmetic products; the occurrence of adverse events associated with microbial contamination of cosmetics; and any other issues relevant to the microbiological safety of cosmetics.

DATES: Submit either electronic or written comments to FDA’s Division of Dockets Management by January 30, 2012. See also “How to Participate in the Meeting” in the **SUPPLEMENTARY INFORMATION** section of this document for important meeting registration deadlines.

ADDRESSES: See Table 1 of this document for meeting location and other information regarding registration for this meeting.

FOR FURTHER INFORMATION CONTACT: For questions about registering for the meeting, to register orally, or to submit a notice of participation by mail, fax, or email: Courtney Treece, Planning Professionals, Ltd., 1210 W. McDermott, suite 111, Allen, TX 75013, (704) 258–4983. Fax: (469) 854–6992, ctreece@planningprofessionals.com.

For questions about the meeting, to request an opportunity to make public comments, to submit the full text, comprehensive outline, or summary of an oral presentation, or to request special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, (240) 402–1731, Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulates cosmetics under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*)

and, for products marketed on a retail basis to consumers, under the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1451 *et seq.*). The law requires that cosmetics be neither adulterated under section 601 of the FD&C Act (21 U.S.C. 361) nor misbranded under section 602 of the FD&C Act (21 U.S.C. 362). That is, they must be safe for consumers under labeled or customary conditions of use and they must be properly labeled. FDA has issued regulations addressing certain aspects of cosmetic safety and labeling (see 21 CFR parts 700, 701, and 740). FDA has also issued guidance regarding certain aspects of cosmetic safety and labeling, including the “Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist” (available at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm>), the “Cosmetic Labeling Manual” (available at <http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/default.htm>), and other cosmetic guidance documents (available at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm>).

FDA has not yet issued specific guidance regarding cosmetic microbiological safety. FDA has presented its preferred laboratory procedures for microbiological analyses of foods and cosmetics in its Bacteriological Analytical Manual (BAM). Chapter 23 of the BAM concerns microbiological methods for cosmetics (available at <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/ucm073598.htm>).