TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1040.10(h)(2)(i) and (h)(2)(ii)		100	1	100	8	800
1040.11(a)(2)		190	1	190	10	1,900
1040.11(c)	FDA 3147	53	2.2	115	0.5	58
1040.20(d), (e)(1), and (e)(2)		110	1	110	10	1,100
1040.30(c)(1)		1	1	1	1	1
1040.30(c)(2)		7	1	7	1	7
1050.10(f)(1) through (f)(2)(iii)		10	1	10	56	560
Total Annual Reporting Burden						89,278

[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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1020.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals					235,679

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

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the ''Estimated Annual Reporting Burden'' table.

The following information collection requirements are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); and 1005.21(a) through (c). These requirements ''apply to the collection of information during the conduct of general investigations or audits'' (5 CFR 1320.4(b)). The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: June 5, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14821 Filed 6–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0727]

Interpretation of On-Farm Feed Manufacturing and Mixing Operations; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal of draft guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry (#77) entitled ''Interpretation of On-farm Feed Manufacturing and Mixing Operations,'' that was issued on September 23, 1998. FDA has decided to withdraw the draft guidance. FDA has decided that the draft guidance did not address adequately the industry

practices of on-farm mixers. Instead, the agency directs you to FDA guidance for industry (#69) entitled ''Small Entities Compliance Guide for Feeders of Ruminant Animals With On-farm Feed Mixing Operations,'' which addresses on-farm mixing practices more completely.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV–214), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0163, e-mail: *nbatalle@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of September 23, 1998 (63 FR 50918), FDA announced the availability of a draft guidance for industry (#77) entitled ''Interpretation of On-farm Feed Manufacturing and Mixing Operations.'' The draft guidance discusses the applicability of certain paragraphs of 21 CFR 589.2000 *Animal proteins prohibited in ruminant feed*. Written comments were to be received by November 23, 1998.

FDA received one letter containing several comments from an industry association on the draft guidance. The comments from the association expressed that they were ''extremely concerned'' that the draft guidance would be ''extremely difficult to monitor and administer'' in the section concerning commingling or cross-contamination of prohibited with nonprohibited mammalian protein. The comment further indicated that the draft guidance did not capture the regulation's requirements regarding equipment clean-out procedures.

After further consideration, FDA has decided to withdraw the draft guidance. FDA has decided that the draft guidance did not address adequately the industry practices of on-farm mixers. Instead, the agency directs you to FDA guidance for industry (#69) entitled ''Small Entities Compliance Guide for Feeders of Ruminant Animals With On-farm Feed Mixing Operations,'' which addresses on-farm mixing practices more completely.

II. Electronic Access

Persons with access to the Internet may obtain FDA guidance for industry #69 at *http://www.fda.gov/cvm/guidance/guidance.html*.

Dated: June 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14820 Filed 6–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0051]

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals With Respect to Antimicrobial Resistance'' (VICH GL27); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#144) entitled ''Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance'' (VICH GL27). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is an initial step in developing harmonized technical guidance in the European Union, Japan, and the United States for approval of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern. The draft guidance outlines the types of studies and data which are recommended for assessing the potential for resistance to develop in association with the use of antimicrobial drugs in food-producing animals.

DATES: Submit written or electronic comments on the draft guidance by July 14, 2003, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), 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 draft guidance document.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail: wflynn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 2002 (67 FR 58058), FDA announced the availability of a related draft guidance for industry (#152) entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern.'' Draft guidance #152 represents FDA's current thinking on an approach for using data, such as that outlined in the VICH draft guidance, for completing an assessment on the safety of antimicrobial drugs that focuses on antimicrobial resistance concerns. The publication of the draft VICH guidance (#144) in the United States was delayed until FDA developed an understanding of how the outlined data could be incorporated into an assessment process such as that described in the FDA draft guidance #152.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval