DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0790]

Final Guidance for Industry: The Use of Published Literature in Support of New Animal Drug Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#106) entitled ''The Use of Published Literature in Support of New Animal Drug Approval.'' The final guidance is intended to fulfill the section of the FDA Modernization Act of 1997 (FDAMA) that requires the agency to issue guidance to clarify the circumstances in which published matter may be the basis for approval of a supplemental application. The final guidance also clarifies the circumstances in which published literature may be the basis for approval of an original application. The final guidance is intended to provide specific advice on when FDA may be able to rely on published literature, with or without the submission of underlying data, to support new animal drug approvals.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the final guidance may be obtained on the Internet at *http://www.fda.gov/cvm/fda/TOCs/guideline.html.*

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20850, 301–594–1620, e-mail: *gschmer1@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 19, 2000 (65 FR 20997), FDA published the draft guidance entitled ''The Use of Published Literature in Support of New Animal Drug Approval'' giving interested persons until July 18, 2000, to submit comments. No comments were received.

Section 403(b) of FDAMA (Public Law 105–115) requires FDA to issue guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for articles approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or section 351 of the Public Health Service Act (42 U.S.C. 262). This provision includes a requirement that FDA publish guidance to clarify circumstances in which published matter may be the basis for approval of a supplemental application.

This final guidance for industry clarifies the circumstances in which published literature may be the basis for approval of both original and supplemental new animal drug applications. Specifically, the final guidance describes the circumstances under which FDA could rely on published literature without access to the underlying data and the circumstances under which the applicant should provide additional information about a published study.

II. Significance of Guidance

This final guidance represents the agency's current thinking with regard to the use of published literature in support of new animal drug approval. 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 method may be used as long as it satisfies the requirements of the applicable statutes and regulations. The agency has developed this final guidance in accordance with the agency's good guidance practices published in the **Federal Register** of September 19, 2000 (65 FR 56468), which set forth the policies and procedures for the development, issuance, and use of guidance documents.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: October 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–28448 Filed 11–6–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Children's Hospital Graduate Medical Education Program (OMB No. 0915–0247)

Public Law 106–129 amended the Public Health Service Act to provide for the support of graduate medical education (GME) in children's hospitals. The provision authorizes payments for direct and indirect expenses associated with operating approved GME programs. Section 340E(c)(1) of the PHS Act, as amended, states that the amount determined under this subsection for payments for direct medical expenses for a fiscal year is equal to the product of (a) the updated per resident amount as determined, and (b) the average number of FTE residents in the hospital's approved graduate medical residency training programs as determined under section 1886(h)(4) of the Social Security Act during the fiscal year. Section 340E(d)(2) requires the Secretary to determine the appropriate amount of indirect medical education for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs to a children's hospital by considering variations in case mix among children's hospitals, and the hospitals' number of FTE residents in approved training programs.

Administration of the Children's Hospital Graduate Medical Education

Program relies on the reporting of the number of full-time equivalent residents in applicant children's hospital training programs to determine the amount of direct and indirect expense payments to participating children's hospitals. Indirect expense payments will also be derived from a formula that requires the reporting of case mix index information from participating children's hospitals.

Hospitals will be requested to submit such information in an annual application. The statute also requires reconciliation of the estimated numbers of residents with the actual number determined at the end of the fiscal year. Participating children's hospitals would be required to complete an adjusted report to correct such information on an annual basis.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form name	Number of respondents	Responses per respondents	Total responses	Hrs. per response	Total hour burden	Wage rate ($/hr)	Total hour cost ($)
HRSA–99–1:	54	1	54	99.9	5,395	45	242,775
(Annual)	54	1	54	8	432	45	19,440
(Reconciliation).							
HRSA–99–2 (IME)	54	1	54	14	756	45	34,020
HRSA–99–4 Required							
GPRA Tables	54	1	54	28	1,512	45	68,040
Total	54	.....	54	.....	8,095		364,275

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, 725 17th St., NW., New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 31, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–28449 Filed 11–06–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Health Service Corps (NHSC) Scholarship Program Deferment Request Forms and Associated Reporting Requirements (OMB No. 0915–0179)—Revision

The National Health Service Corps (NHSC) Scholarship Program was established to assure an adequate supply of trained primary care health professionals to the neediest communities in the Health Professional Shortage Areas (HPSAs) of the United States. Under the program, allopathic physicians, osteopathic physicians, dentists, nurse practitioners, nurse midwives, physician assistants, and, if needed by the NHSC program, students of other health professionals are offered the opportunity to enter into a contractual agreement with the Secretary under which the Public Health Service agrees to pay the total school tuition, required fees and a stipend for living expenses. In exchange, the scholarship recipient agrees to provide full-time clinical services at a site in a federally designated HPSA.

Once the scholars have met their academic requirements, the law requires that individuals receiving a degree from a school of medicine, osteopathic medicine or dentistry be allowed to defer their service obligation for a maximum of 3 years to complete approved internship, residency or other advanced clinical training. The Deferment Request Form provides the information necessary for considering the period and type of training for which deferment of the service obligation will be approved.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Deferment Request Forms	600	1	1	600
Letters of Intent and Request	100	1	1	100
Total	700			700

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 31, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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