The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, on or before November 2, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Comments should be identified with the docket number found in brackets in the heading of this document.

Dated: July 20, 1999

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–19976 Filed 8–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0017]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Guidance on Validation of Analytical Procedures: Methodology; 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 entitled ''Validation of Analytical Procedures: Methodology.'' This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from an identically titled guidance adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and published in the **Federal Register**. The guidance provides recommendations on how to consider various validation characteristics for each analytical procedure included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time.

ADDRESSES: Copies of the final guidance document entitled ''Validation of Analytical Procedures: Methodology'' may be obtained on the Internet from the CVM home page at ''http://www.fda.gov/cvm/fda/TOCs/guideline.html''. Persons without Internet access may 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 the final guidance document to the Policy and Regulations Team (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Regarding this guidance: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966, e-mail ''wmarnane@cvm.fda.gov''.

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail ''sthompso@cvm.fda.gov''.

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

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary pharmaceutical products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Épizooties (OIE). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee. The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, one representative from industry in Australia/New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay, and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from an identically titled guidance adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and published in the **Federal Register** of May 19, 1997 (62 FR 27464).

In the **Federal Register** of January 27, 1998 (63 FR 3907), FDA published this guidance in draft form, giving interested persons until March 30, 1998, to submit comments. After consideration of comments received, a final draft guidance was submitted to the VICH Steering Committee.

At a meeting held on October 20 through 22, 1998, the VICH Steering Committee endorsed the draft guidance for industry entitled ''Validation of Analytical Procedures: Methodology.'' This guidance discusses common analytical procedures and provides guidance and recommendations on how to consider the various validation characteristics for each analytical procedure included as part of a registration application for approval of veterinary medicinal products. It also indicated the various data that should

be included in registration applications. This guidance will be implemented in October 1999.

This guidance represents the agency's current thinking on characteristics for consideration during the validation of the analytical procedures included as part of applications. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate approach may be used if it satisfies the requirements of applicable statutes, regulations, or both.

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

Dated: July 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19977 Filed 8–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1054–N]

RIN 0938–AJ62

Medicare Program; Hospice Wage Index

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the annual update to the hospice wage index as required by statute. This update is effective October 1, 1999. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published in the **Federal Register** on August 8, 1997. This update is the third year of a 3-year transition period. The third transition year begins October 1, 1999 and ends September 30, 2000.

EFFECTIVE DATE: This notice is effective on October 1, 1999.

FOR FURTHER INFORMATION CONTACT: Carol Blackford, (410) 786–5909

SUPPLEMENTARY INFORMATION:

I. Background

A. Statute and Regulations

Hospice Care is an approach to treatment that recognizes that the impending death of an individual warrants a change in the focus from curative care to palliative care (relief of pain and other uncomfortable symptoms). The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, social, psychological, emotional, and spiritual services through use of a broad spectrum of professional and other caregivers, with the goal of making the individual as physically and emotionally comfortable as possible. Counseling and respite services are available to the family of the hospice patient. Hospice programs consider both the patient and the family as a unit of care.

Section 1861(dd) of the Social Security Act (the Act) provides for coverage of hospice care for terminally ill Medicare beneficiaries who elect to receive care from a participating hospice. The statutory authority for payment to hospices participating in the Medicare program is contained in section 1814(i) of the Act.

Our regulations at 42 CFR part 418 (issued on December 16, 1983, effective for hospice services furnished on or after November 1, 1983) established eligibility requirements and payment standards and procedures, defined covered services, and delineated the conditions a hospice must meet to be approved for participation in the Medicare program. Subpart G of part 418 provides for payment to hospices based on one of four prospectively determined rates for each day in which a qualified Medicare beneficiary is under the care of a hospice. The four rate categories are routine home care, continuous home care, inpatient respite care, and general inpatient care. Payment rates are established for each category.

Section 4442 of the Balanced Budget Act of 1997, Public Law 105–C3, amended section 1814 (i)(2) of the Act to require payment for routine and continuous home care to be made based on the geographic location at which the service is furnished. The site of service provision was effective October 1, 1997 and was implemented through a Program Memorandum (transmittal A–97–11) issued in September of 1997.

Section 418.306(c), that requires the rates to be adjusted by a wage index, was revised on August 8, 1997, through publication of a final rule in the **Federal Register** (62 FR 42860). This rule implemented a new methodology for calculating the hospice wage index that was based on the recommendations of a negotiated rulemaking committee. The committee reached consensus on a methodology and the resulting committee statement, describing that consensus, was included as an attachment to the August 8, 1997 hospice wage index final rule. The provisions of the final hospice wage index rule are as follows:

- The revised hospice wage index will be phased in over a 3-year transition period. For the first year of the transition period, a blended index was calculated by adding two-thirds of the 1983 index value for an area to one-third of the revised wage index value for that area. During the second year of the transition period, the calculation was similar, except that the blend was one-third of the 1983 index value and two-thirds of the revised wage index value for that area. During the third transition year, the revised wage index will be fully implemented. The first transition year occurred October 1, 1997 through September 30, 1998. The second transition year occurred October 1, 1998 through September 30, 1999.
- All hospice wage index values of 0.8 or greater are subject to a budget neutrality adjustment to ensure that Medicare does not pay any more in the aggregate than it would have paid with the previous wage index. The budget neutrality adjustment is calculated by multiplying the hospice wage index for a given area by the budget neutrality adjustment factor. The budget neutrality adjustment is to be applied annually, both during and after the transition period.
- All hospice wage index values below 0.8 receive the greater of the following adjustments—the wage index floor, a 15 percent increase, subject to a maximum wage index value of 0.8; or, the budget neutrality adjustment.
- The wage index is to be updated annually, in the **Federal Register**, based on the most current available hospital wage data.

B. Update to the Hospice Wage Index

The third year of the 3-year transition period begins October 1, 1999 and ends September 30, 2000. In accordance with the agreement signed by members of the Hospice Wage Index Negotiated Rulemaking Committee, we are using 1998 hospital area wage index data, including any changes to the definitions of Metropolitan Statistical Areas