EA, or it may require an EA or an environmental impact statement (EIS), or it may require both.

Using the terminology of the draft guidance document, a Phase I EIA is equivalent under NEPA to either a categorical exclusion or an EA that addresses only environmental exposures (40 CFR 1508.4 and 1508.9). A Phase II EIA represents an EA with more extensive data than would be necessary under the U.S. equivalent of a Phase I EIA. A Phase II EIA may lead to a finding of no significant impact or preparation of an EIS under NEPA.

Questions 2, 3, and 4 of the VICH guidance, which respectively address natural substances, nonfood animals, and minor species, directly parallel existing categorical exclusions under NEPA. (See § 25.33(c), (d)(1), and (d)(4).) These classes of actions have been determined not to have significant environmental impacts. Similarly, question 5, which concerns VMP's used to treat a small number of animals, generally parallels categorical exclusions in § 25.33(d)(2), (d)(3), (d)(4), and (d)(5). These questions provide guidance for defining when a categorical exclusion may be appropriate for U.S. environmental reviews.

Even when a VMP might ordinarily be categorically excluded under NEPA, there may be extraordinary circumstances that require the submission of an EA. Questions 11 through 13 and 17 provide guidance on when such extraordinary circumstances exist. Specifically, questions 11 through 13 relate to whether the environmental introduction concentration ($EIC_{aquatic}$) of a VMP released from aquaculture facilities is less than 1 microgram/liter (µg/L). Similarly, question 17 relates to whether the predicted environmental concentration in soil ($PEC_{soil}$) for VMP's used in terrestrial species is less than 100 µg/kilogram (kg). Based upon information reviewed to support the guidance, $EIC_{aquatic}$ at or above 1 µg/L, or $PEC_{soil}$ at or above 100 µg/kg, could result in an environmental exposure concentration that could potentially have significant impact on the environment. Thus, an $EIC_{aquatic}$ equal to or greater than 1 µg/L or a $PEC_{soil}$ equal to or greater than 100 µg/kg represents a level of exposure that constitutes extraordinary circumstances that require the submission of an EA or an EIS (see § 25.21(a)).

Additionally, for questions 11 through 13 and 17, FDA is concerned that if the VMP is not expected to degrade or may bioconcentrate, then the aggregate level of exposure from repeated uses could exceed the 1 µg/L $EIC_{aquatic}$ or the 100 µg/kg $PEC_{soil}$ guidance. FDA is seeking comment on how to address the degradability and bioconcentration of a VMP when applying these guidance.

There are no categorical exclusions which parallel questions 6 through 17. Consequently, an EA to address the issues identified in these questions will be required under NEPA for U.S. environmental review. The EA must provide data demonstrating that any conditions of the question (e.g., the VMP is extensively metabolized in the treated animal) or any proposed mitigations (e.g., waste disposal by incineration or sewage treatment) will result in no significant environmental impacts from the VMP.

FDA specifically requests comment on questions 8 and 14 and the text following these questions because FDA is concerned that the text might create the mistaken impression that any time incineration is used to dispose of a waste matrix, there will be no significant impact on the environment under NEPA. For any mitigation, including incineration, the sponsor needs to provide data in the EA that demonstrates that the mitigating measures do in fact ensure that the VMP has no significant impact on the environment.

CVM will provide more detailed guidance, including guidance on formatting for EA's submitted to the United States, guidance on other extraordinary circumstances, and guidance on other NEPA-related environmental issues, such as impacts on natural and historical resources.

Comments about this draft guidance document will be considered by FDA and the VICH Ecotoxicity Working Group. Ultimately, FDA intends to adopt and publish the VICH Steering Committee's final guidance.

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practice regulations (62 FR 8961, February 27, l997) . For example, the document has been designated ''guidance'' rather than ''guideline.'' Since guidance documents are not binding, mandatory words such as ''must'' and ''shall,'' and ''will'' in the original VICH document have been substituted with ''should.'' Additionally, the term(s) ''veterinary medicinal products'' and ''veterinary pharmaceuticals products'' may require revision to be consistent with product terms used in other VICH guidance documents.

This draft guidance document represents a portion of FDA's current thinking on the conduct of ecological risk assessment for veterinary medicinal products proposed for marketing in the European Union, Japan, and the United States. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

### III. Comments

General comments on agency guidance documents are welcome at any time. However, in order to ensure consideration at the next meeting, interested persons should submit written comments on or before October 18, 1999, to the Dockets Management Branch (address above) regarding this draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 10, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99–24208 Filed 9–16–99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–R–0232]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or

other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension; *Title of Information Collection:* Supporting Statement for Medicare Program Integrity Program Organizational Conflict of Interest Disclosure Certificate and Supporting Regulations in 42 CFR 421.310 and 421.312;

*Form No.:* HCFA–R–0232 (OMB# 0938–0723); *Use:* This information is used to assess whether contractors who perform, or who seek to perform, Medicare Integrity Program functions, such as medical review, fraud review or cost audits, have organizational conflicts of interest and whether any conflicts have been resolved. The entities providing the information will be organizations that have been awarded, or seek award of, a Medicare Integrity Program contract; *Frequency:* On occasion; *Affected Public:* Businesses or other for profit; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 2,400.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 9, 1999.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 99–24220 Filed 9–16–99; 8:45 am]

BILLING CODE 4120–03–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–1964]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* Request for Review of Part B Medicare Claim and Supporting Regulations in 42 CFR 405.807;

*Form No.:* HCFA–1964 (OMB# 0938–0033);

*Use:* The HCFA–1964 is a form which is used nationally to request review of an initial determination made on a Part B health insurance claim. A Medicare beneficiary (or his/her physician/supplier who accepts assignment) files for Part B benefits using forms HCFA–1490S (Patient's Request for Medicare Payment), HCFA–1491 (Request for Medicare Payment—Ambulance), or HCFA–1500 (Health Insurance Claim Form). If any benefits are denied, the claimant has the right to request a review of the initial determination by submitting this HCFA–1964, form.;

*Frequency:* On occasion;

*Affected Public:* Individuals or Households, and Not-for-profit institutions;

*Number of Respondents:* 5,600,000;

*Total Annual Responses:* 5,600,000;

*Total Annual Hours:* 1,400,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 9, 1999.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services,Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 99–24269 Filed 9–16–99; 8:45 am]

BILLING CODE 4120–03–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–R–0286]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension; *Title of Information*