

and biological products, the agency published a final rule in the **Federal Register** of October 7, 1997 (62 FR 52237), amending these requirements, as well as others, to implement certain definitions, reporting periods, and formats recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In addition, FDA published a final rule in the **Federal Register** of June 25, 1997 (62 FR 34166), that revokes the postmarketing safety reporting requirement to submit increased frequency reports for human drug and biological products in an expedited manner. This draft guidance for industry revises the agency's existing guidances on postmarketing safety reporting to be consistent with the final rules of June 25, 1997, and October 7, 1997.

At this time, the agency is considering additional recommendations developed by ICH and plans to propose other amendments to its postmarketing safety reporting regulations. As additional amendments are made to these regulations, the agency intends to develop guidances for industry to provide recommendations on how industry can fulfill these requirements.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on postmarketing safety reporting for human drug and biological products including vaccines. 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 approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance.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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The

information requested for marketed human drug and biological products is already covered by the collection of information on postmarketing safety reporting regulations (§§ 310.305, 314.80, 600.80, and 600.81) submitted to the Office of Management and Budget (OMB) for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection for MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) and assigned it OMB control number 0910–0291. The approval for 0910–0291 expires on March 31, 2001; an extension has been requested and is pending at OMB. OMB also approved the information collection for adverse experience reporting for marketed drugs and licensed biological products and assigned them OMB control numbers 0910–0230 and 0910–0308, respectively. The approval for 0910–0230 expires on May 31, 2002, and the approval for 0910–0308 expires on May 31, 2001.

IV. Electronic Access

Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> and at <http://www.fda.gov/cber/guidelines.htm>.

Dated: March 2, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10008]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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 previously approved collection;

Title of Information Collection: Recognition of New Technology/Pass-Through Items Under the Prospective Payment System for Hospital Outpatient Services;

Form No.: HCFA–10008 (OMB# 0938–0802);

Use: This information is necessary to determine items eligible for payment as new technology within the ambulatory payment classification (APC) system as well as items eligible for the transitional pass-through payment provision as required by section 201 of the BBRA. This collection will enable HCFA to implement those special payment provisions;

Frequency: On Occasion;

Affected Public: Business or other for-profit;

Number of Respondents: 500;

Total Annual Responses: 500;

Total Annual Hours: 1,500.

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: Melissa Musotto, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 1, 2001.

John P. Burke, III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

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