

office when the Associate Commissioner for OHA determines that appearances at hearings conducted in the areas can be conducted more efficiently by VTC than in person. However, while the Associate Commissioner makes the decision about the general efficiency of using VTC in an area, the ALJ is responsible for determining if using VTC for any appearance in a particular case will be efficient.

Comment: The same organization also commented that our rules should require the hearing notice to include a statement that a ME and/or a VE will appear by VTC and provide an opportunity to object.

Response: Sections 404.938(b) and 416.1438(b) of the final rules with request for comment specify that the claimant "will also be told if [his/her] appearance or that of any other party or witness is scheduled to be made by [VTC] rather than in person." We reflect these requirements in HALLEX guidance that modifies our standardized notices of hearing to notify claimants that a witness will appear by VTC and to advise them explicitly of their right to object to any aspect of the hearing (see Footnote 7 above).

Regulatory Procedures

Executive Order 12866, As Amended by Executive Order 13258

We have consulted with the Office of Management and Budget (OMB) and determined that this final rules document meets the criteria for a significant regulatory action under Executive Order 12866, as amended by Executive Order 13258. Thus, it was reviewed by OMB.

Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities as they affect individuals only. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 says that no persons are required to respond to a collection of information unless it displays a valid OMB control number. In accordance with the PRA, SSA is providing notice that the Office of Management and Budget has approved the information collection requirements contained in §§ 404.929, 404.936(d), (e) & (f), 404.938(c) (HA-504), 404.950(a), 416.1429, 416.1436(d), (e) and (f), 416.1438(c) (HA-504), and 416.1450(a) of these final rules. The OMB control

number for this collection is 0960-0671, expiring November 30, 2004.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.003, Social Security-Special Benefits for Persons Aged 72 and Over; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Aged, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: October 3, 2003.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ Accordingly, the final rules with request for comment amending 20 CFR parts 404 and 416 that were published at 68 FR 5210 on February 3, 2003, are adopted as final rules without change.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 2000N-1652]

RIN 0910-AB91

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the format in which certain labeling is required to be submitted for review with new drug applications (NDAs), certain biological license applications (BLAs), abbreviated new drug applications (ANDAs), supplements, and annual reports. The final rule requires that certain labeling content be submitted electronically in a

form that FDA can process, review, and archive. Submitting the content of labeling in electronic format will simplify the drug labeling review process and speed up the approval of labeling changes.

DATES: The rule is effective June 8, 2004.

FOR FURTHER INFORMATION CONTACT:

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Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 3, 2002 (67 FR 22367), FDA published a proposed rule to require the submission of the content of labeling for human prescription drugs and certain biologics in electronic format in a form that FDA can process, review, and archive. This electronic submission requirement would necessitate the amendment of FDA's regulations under §§ 314.50(l) (21 CFR 314.50(l)), 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)), 314.94(d)(1) (21 CFR 314.94(d)(1)), and the addition of § 601.14 (21 CFR 601.14).

Under current regulations, as noted in the preamble to the proposed rule, labeling for the archival copy of an NDA must be submitted to the agency on paper, labeling for the archival copy of an ANDA may be submitted in any form that FDA and the applicant agree upon, and the current regulations for BLA labeling do not specify a format for submission to the agency. The term "labeling" used in §§ 314.50, 314.94, 314.81, and § 601.12 is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(m)) to mean both labels¹ and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. Thus, requiring the submission of "labeling" entails submission of the label (i.e., the label on the immediate container) and labeling. Labeling consists of the comprehensive prescription drug labeling directed to health care practitioners (i.e., the labeling required under § 201.100(d)(3) (21 CFR 201.100(d)(3)), commonly referred to as the "package insert" or

¹ Under section 201(k) of the act, the term "label" means a display of written, printed, or graphic matter upon the immediate container of any article.