

**ESTIMATED STATE MEDIAN INCOME  
FOR 4-PERSON FAMILIES, BY STATE,  
FISCAL YEAR 2001 <sup>1</sup>—Continued**

States	Estimated state median income 4- person families <sup>2</sup>	60 per- cent of estimated state median income 4- person families
Wyoming .....	50,989	30,593

<sup>1</sup> In accordance with 45 CFR 96.85, each State's estimated median income for a 4-person family is multiplied by the following percentages to adjust for family size: 52% for one person, 68% for two persons, 84% for three persons, 100% for four persons, 116% for five persons, and 132% for six persons. For family sizes greater than six persons, add 3% for each additional family member and multiply the new percentage by the State's estimated median income for a 4-person family.

<sup>2</sup> Prepared by the Bureau of the Census from the March 1999 Current Population Survey, 1990 Decennial Census of Population and Housing, and 1998 per capita personal income estimates, by state, from the Bureau of Economic Analysis.

Note—FY 2001 covers the period of October 1, 2000 through September 30, 2001. The estimated median income for 4-person families living in the United States is \$56,061 for FY 2001. The estimates are effective for the Low Income Home Energy Assistance Program (LIHEAP) at any time between the date of this publication and October 1, 2000, or by the beginning of a LIHEAP grantee's fiscal year, whichever is later.

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00D-0835]

**Draft Guidance for Industry on  
Conjugated Estrogens, USP: LC-MS  
Method for Both Qualitative Chemical  
Characterization and Documentation of  
Qualitative Pharmaceutical  
Equivalence; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Conjugated Estrogens, USP: LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence." This draft guidance is intended to provide recommendations to applicants who wish to submit a new drug application or abbreviated new drug application for

a natural source conjugated estrogens solid oral dosage form. This guidance provides a description of the liquid chromatography-mass spectrometry (LC-MS) method that can be used to address both qualitative chemical characterization and qualitative pharmaceutical equivalence (PE).

**DATES:** Submit written comments on the draft guidance by June 8, 2000. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Wallace P. Adams, Center for Drug Evaluation and Research (HFD-350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5651.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled "Conjugated Estrogens, USP: LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence." Chemical characterization and PE of natural source conjugated estrogens involve both qualitative and quantitative aspects. Qualitative aspects of both chemical characterization and PE involve detection and measurement of certain of the components in conjugated estrogens. The recommended methodology, LC-MS, is applicable to both the drug substance and/or solid oral dosage forms. This draft guidance provides a description of the LC-MS method developed by the Division of Testing and Applied Analytical Development/Office of Pharmaceutical Science/Center for Drug Evaluation and Research for both the qualitative chemical characterization and documentation of qualitative PE of natural source conjugated estrogens. Interpretation of the data for PE is beyond the scope of this guidance and will be addressed in a separate document. Quantitative aspects of chemical characterization and PE use

the gas chromatography (GC) (flame-ionization detector) and high-pressure liquid chromatography (HPLC) (ultraviolet detector) assays described in a draft proposed Conjugated Estrogens, USP, monograph (<http://www.fda.gov/cder/drug/monographs/default.htm>), and they are not the subject of this guidance.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on this LC-MS method for both qualitative chemical characterization and documentation of qualitative pharmaceutical equivalence of conjugated estrogens, USP. 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 requirements of the applicable statutes, regulations, or both.

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.

Dated: March 1, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Health Care Financing Administration**

[Document Identifier: HCFA-R-205/  
Supplement]

**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:* New Collection; *Title of Information Collection:* Individual Market-Guarantee Issue Election Packet, and Supporting Regulations in 45 CFR 148, and Forms/Instructions; *Form No.:* HCFA-R-205/Supplement (OMB #0938-NEW); *Use:* This collection is a Supplement of the existing collection for "Information Collection Requirements Referenced in HIPAA for the Individual Market, Supporting Regulations in 45 CFR 148, and forms/instructions (OMB 0938-0703). This supplement is intended to simplify the filing obligations of issuers who participate in the individual market of more than one direct enforcement state. A direct enforcement state is a state in which HCFA has the responsibility to enforce the requirements of HIPAA. This supplement allows the issuer to submit the requested information for multiple states at one time, rather than having to complete a separate transmittal form for each state; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Individuals or Households, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 15; *Total Annual Responses:* 150; *Total Annual Hours:* 566.

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](mailto: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 Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850

Dated: February 29, 2000.

**John P. Burke III,**

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

[FR Doc. 00-5703 Filed 3-8-00; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-1514]

#### 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 currently approved collection; *Title of Information Collection:* Hospital Request for Certification in the Medicare/Medicaid Program;

*Form No.:* HCFA-1514 (OMB# 0938-0380); *Use:* Section 1861 of the Social Security Act requires hospitals and critical access hospitals to be certified to participate in the Medicare/Medicaid program. These providers must complete the "Hospital Request for Certification in the Medicare/Medicaid Program" form in order to be certified or recertified; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions;

*Number of Respondents:* 6,300; *Total Annual Responses:* 4,400; *Total Annual Hours:* 1,100.

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](mailto: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: February 28, 2000.

**John P. Burke III,**

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

[FR Doc. 00-5704 Filed 3-8-00; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-0368 and HCFA-R-0144]

#### 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