ESTIMATED STATE MEDIAN INCOME FOR 4-PERSON FAMILIES, BY STATE, FISCAL YEAR 2001 [1]—Continued

States	Estimated state median income 4-person families [2]	60 percent of estimated state median income 4-person families
Wyoming	50,989	30,593

[1] 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.

[2] 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Draft Guidance for Industry on Conjugated Estrogens, USP: LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Conjugated Estrogens, USP: LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical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 This draft guidance is intended to provide recommendations to applicants who wish to submit a new drug application or abbreviated new drug application for a natural source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 chromotography (GC) (flame-ionization detector) and high-pressure liquid chromotography (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