

and Annually; *Affected Public*: State, Local or Tribal Government and Not-for-profit institutions; *Number of Respondents*: 298; *Total Annual Responses*: 836; *Total Annual Hours*: 6,440.

5. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Physician Group Practice (PGP) Standardized Ambulatory Care Quality Measure Collection Initiative; *Use*: The Benefits Improvement & Protection Act of 2000 mandated the Physician Group Practice (PGP) Demonstration and gave the Secretary discretion to use quality measures to assess physician performance in order to reward them for improvements in the quality and efficiency of health care. This demonstration is intended to strengthen the Medicare program by offering innovative models to beneficiaries that improve quality and access and lower costs. As a result, Medicare beneficiaries will directly benefit from these innovative models. The demonstration represents the first pay for performance project for physician group practices and will enable comparisons across groups and geography; *Form Number*: CMS-10134 (OMB #0938-0942); *Frequency*: Annually; *Affected Public*: Business or other for-profit and Not-for-profit institutions; *Number of Respondents*: 10; *Total Annual Responses*: 10; *Total Annual Hours*: 790.

6. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Internal Revenue Service/Social Security Administration/Centers for Medicare and Medicaid Services Data Match and Supporting Regulations in 42 CFR 411.20-491.206; *Form No.*: CMS-R-137 (OMB #0938-0565); *Use*: The Data Match project and information collection activity provides a "check and balance" against the Medicare program relying solely on a single information collection system. It gives CMS the opportunity to pursue collection of identified mistaken payments (within legal constraints) and to update incorrect status indicators to prevent further incorrect suspensions or mistaken payment or denial. Employers identified through a match of IRS, SSA, and Medicare records will be contacted concerning group health plan coverage of identified individuals to ensure compliance with Medicare Secondary Payer provisions found at 42 U.S.C. 1395y(b); *Frequency*: Reporting—Annually; *Affected Public*: Business or

other for-profit, Not-for-profit institutions, Farms, Federal, State, Local or Tribal Government; *Number of Respondents*: 341,065; *Total Annual Responses*: 341,065; *Total Annual Hours*: 1,986,810.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/regulations/ptra/>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.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 to the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 5, 2005.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2000D-0835]

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

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

**ACTION**: Notice; withdrawal.

**SUMMARY**: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry entitled "Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence." FDA is withdrawing the draft guidance because the published methodology limits the submission of scientifically valid information to the agency that may be based on different methodologies. FDA does not want to dictate the scientific approach for developing adequate methods.

**FOR FURTHER INFORMATION CONTACT**: David J. Cummings, Center for Drug Evaluation and Research (HFD-357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5187.

**SUPPLEMENTARY INFORMATION**: FDA is announcing the withdrawal of a draft guidance for industry entitled "Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence." The agency announced the availability of the guidance in the **Federal Register** of March 9, 2000 (65 FR 12556). The draft guidance was originally intended to provide recommendations to applicants on how to use the liquid chromatography mass spectrometry (LC-MS) method to address both qualitative chemical characterization and qualitative pharmaceutical equivalence for natural source conjugated estrogens. FDA is withdrawing the guidance because advances in technology allow for the possibility of using different methodologies. FDA does not want to inhibit companies from using a methodology that might provide additional scientific data to support characterization and pharmaceutical equivalence for conjugated estrogens in the future. If submitted, these data would be evaluated to determine applicability of the method before an application could be approved.

Dated: August 5, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2005-22049]

#### **Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Numbers: 1625-0035 and 1625-0051**

**AGENCY**: Coast Guard, DHS.

**ACTION**: Request for comments.

**SUMMARY**: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of two Information Collection Requests (ICRs). The ICRs are for 1625-0035, Title 46 CFR Subchapter Q: Lifesaving, Electrical, and Engineering Equipment, Construction and Materials & Marine