

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D-0835]

DDM

Display Date	8-11-05
Publication Date	8-12-05
Officer	R. LEONARD

**Draft Guidance for Industry on Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical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

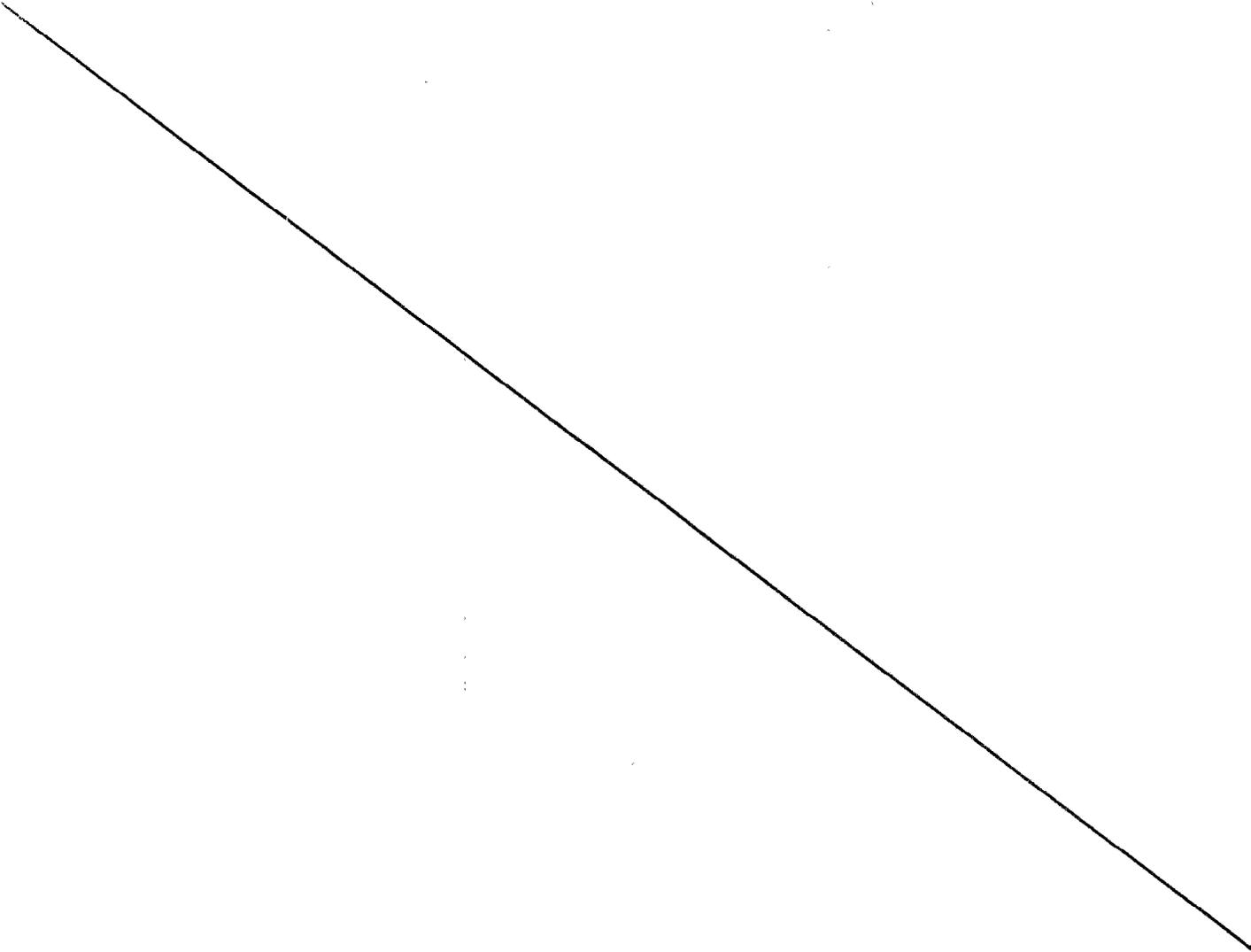
---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry entitled "Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical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 FDA is withdrawing the draft guidance because the published methodology limits the submission of scientifically valid information to the agency that may be based on different methodologies.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.

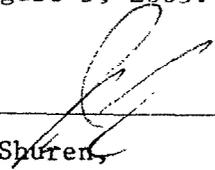
**SUPPLEMENTARY INFORMATION:** FDA is announcing the withdrawal of a draft guidance for industry entitled "Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence." The agency announced the availability of the guidance 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: 8/5/05

August 5, 2005.

  
\_\_\_\_\_  
Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**  
