

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory Priorities

The Department of Health and Human Services (HHS) conducts a broad range of programs mandated by Congress to protect and promote the health and well-being of all Americans, focused especially on those least able to help themselves. HHS responsibilities include: Medicare, Medicaid, support for public health preparedness, biomedical research, substance abuse and mental health treatment, assurance of safe and effective drugs and other medical products, food safety, financial assistance to low income families, Head Start, services to older Americans, and direct health services delivery.

Since assuming the leadership of HHS, Secretary Michael O. Leavitt has consistently sought to make transparent his approach to overseeing the Department's programs, through his use of a 500-Day Plan and a recent statement of his nine major priorities. The 500-Day Plan and the statement of priorities are available for public review at <http://www.hhs.gov/secretaryspage.html>. The regulatory actions noted below reflect this policy framework.

Health Information Technology

The Secretary's strategy for promoting improvements in the Nation's health sector stresses maximum use of electronic information technology. The FY 2007 Regulatory Plan accordingly includes a notice of proposed rulemaking to require that clinical study data be provided to the Food and Drug Administration (FDA) in electronic format, using standard data structures, terminology, and code sets. The change would further increase the efficiency of the agency's review processes, speeding up the availability of new therapies. Additionally, the Plan includes: proposed actions to require medical device firms to register electronically with the FDA, as well as to report post-marketing information to the agency electronically; and a proposal for the adoption of final standards for the electronic transmission of basic prescription-drug data.

Medicare Modernization

The Secretary's statement of priorities includes a focus on Medicare modernization. The Regulatory Plan, accordingly, highlights:

- a proposal to institute competitive bidding procedures to improve the effectiveness of Medicare's current methodology for setting payment amounts for durable medical equipment; and
- final rules for hospital inpatient services for fiscal year 2008 and for long-term-care hospital services for rate year 2008.

Medicare Part D

The Secretary believes that every senior must have access to affordable prescription drugs, and that a reinforced regulatory framework for implementing the Medicare prescription drug benefit can further connect beneficiaries with the Part D program. The Plan accordingly includes a

proposal to clarify current provisions affecting Part D Prescription Drug Plan sponsors and Medicare Advantage organizations, and the above-cited proposal for the adoption of final standards for the electronic transmission of basic prescription-drug data.

Disease Prevention

Also included among the Secretary's priorities is an emphasis on disease prevention and the need for individual responsibility for personal wellness. Three actions in the Plan reflect this concern:

- a final rule establishing good manufacturing practices for the dietary-supplement products favored by many Americans;
- a proposal to modify prescription drug labeling so that health care providers may better understand and communicate to their patients the risks and benefits associated with the use of prescribed medicines during pregnancy and lactation, and
- a proposal to amend existing regulations governing investigational new drugs — the rule would delineate new avenues of access for patients to obtain investigational drugs for treatment use.

Food Safety

The Secretary's 500-Day Plan also embraces the need to secure the homeland. The Regulatory Plan thus includes:

- a proposal to require owners or consignees to label imported food that has previously been refused entry into the United States. This action would prevent the introduction of unsafe food and facilitate the examination of imported food; and
- a final rule completing the rulemaking process requiring that the FDA be notified prior to the entry of imported food into the United States.

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HHS—Food and Drug Administration (FDA)

PROPOSED RULE STAGE

36. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96

Legal Deadline: None

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments be provided in an electronic format that

FDA can process, review, and archive. The proposal would also require the use of standardized data structure, terminology, and code sets contained in current FDA guidance (the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium) to allow for more efficient and comprehensive data review.

Statement of Need: Before a drug is approved for marketing, FDA must determine that the drug is safe and effective for its intended use. This determination is based in part on clinical study data and bioequivalence data that are submitted as part of the marketing application. Study data submitted to FDA in electronic format have generally been more efficient to process and review.

FDA's proposed rule would require the submission of study data in a standardized electronic format, and it provides that the specific format will be announced in FDA guidance. Electronic submission of study data would improve patient safety and enhance health care delivery by enabling FDA to process, review, and archive data more efficiently. Standardization would also enhance the ability to share study data and communicate results. Investigators and industry would benefit from the use of standards throughout the lifecycle of a study—in data collection, reporting, and analysis. The proposal would work in concert with ongoing agency and national initiatives to support increased use of electronic technology as a means to improve patient safety and enhance health care delivery.

Summary of Legal Basis: Our legal authority to amend our regulations governing the submission and format of clinical study data and bioequivalence data for human drugs and biologics derives from sections 505 and 701 of the act (U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262).

Alternatives: FDA considered issuing a guidance document outlining the electronic submission and the standardization of study data, but not requiring electronic submission of the data in the standardized format. This alternative was rejected because the agency would not fully benefit from standardization until it became the industry standard, which could take up to 20 years.

We also considered a number of different implementation scenarios, from shorter to longer time-periods. The two-year time-period was selected because the agency believes it would provide ample time for applicants to comply without too long a delay in the effective date. A longer time-period would delay the benefit from the increased efficiencies, such as standardization of review tools across applications, and the incremental cost saving to industry would be small.

Anticipated Cost and Benefits: Approximately 70 percent of study data for NDAs and ANDAs are already submitted to FDA in electronic format consistent with our current guidance on electronic submission of data. The other 30 percent is either submitted on paper or in non-standardized electronic format. FDA estimates that the costs to industry resulting from the proposal would include some one-time costs and possibly some annual recurring costs. One-time costs would include, among other things, the cost of converting data to standard structures, terminology, and cost sets (i.e., purchase of software to convert data); the cost of submitting electronic data (i.e., purchase of file transfer programs); and the cost of installing and validating the software and training personnel. Additional annual recurring costs may result from software purchases and licensing agreements for use of proprietary terminologies.

The proposal could result in many long-term benefits for industry, including improved patient safety through faster, more efficient, comprehensive, and accurate data review; enhanced communication among sponsors and clinicians.

Risks: None.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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