

B. Section 20.34—Search for Records

The proposal stated that in responding to a request for records, the agency shall make reasonable efforts to search for records kept in their electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems.

The comment recommended that the agency provide an example of the kind of requests FDA believes would significantly interfere with the operation of the agency's automated information systems.

It is not readily possible for FDA to provide examples of situations that would significantly interfere with the operation of the agency's automated information systems. Because FDA has a decentralized system for processing FOIA requests, what constitutes significant interference may depend on the technical capabilities and resources of the particular office processing a request. Thus, the agency will be making these decisions on a case by case basis.

C. Section 20.40—Filing a Request for Records

As stated in the proposal, FDA will accept FOI requests via facsimile as well as via mail.

The comment requested that FDA also add e-mail as an acceptable means of filing a FOIA request in light of the common use of e-mail in today's business world. The agency is exploring the possibility of accepting electronic FOI requests, and at some future time may amend its regulations to permit the filing of electronic requests.

D. Section 20.44—Expedited Processing

The proposal implements section 8 of EFOIA, which requires agencies to provide for expedited processing of FOIA requests in cases where the person requesting the records demonstrates a "compelling need" and in other cases as determined by the agency.

The comment expressed concern that the scope of individuals or entities that can demonstrate "compelling need" is too narrow. In particular, the comment stated that the rule should be restructured so that pharmaceutical and other healthcare companies would also be in a position to obtain expedited processing when there is an urgency to inform the public about FDA regulatory activity, such as product recalls.

The definition of "compelling need" is set forth in the EFOIA statute (5 U.S.C. 552(a)(6)(E)) itself and cannot be changed by agency rulemaking.

However, because EFOIA also permits agencies to grant expedited processing in other cases as determined by the agency, in those instances where the requester does not meet the statutory definition of "compelling need" but demonstrates a need for expedited processing, the agency has the discretion to grant such requests.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule provides for greater flexibility in making requests,

increased access to public information, and in certain cases, a faster agency response, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million, adjusted annually for inflation. As noted above, we find that this final rule would not have an effect of this magnitude on the economy.

VI. Paperwork Reduction Act of 1995

The final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects*21 CFR Part 10*

Administrative practice and procedure, News media.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 720

Confidential business information, Cosmetics.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Freedom of Information Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 10, 14, 20, 314, and 720 are amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112, 42 U.S.C. 201, 262, 263b, 264.