

Bristol-Myers Squibb Pharmaceutical Research Institute

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February 1, 2000

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Laurie Smaldone, M.D.
Senior Vice President
Worldwide Regulatory Affairs

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket No. 99N-2637; Proposed Rule, Public Information Regulation, [*Federal Register*, Vol. 64, No. 213, November 4, 1999]

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, beauty care, nutritionals and medical devices. We are a leading company in the development of innovative therapies for cardiovascular, metabolic, oncology, infectious diseases, and neurological disorders.

The Bristol-Myers Squibb Pharmaceutical Research Institute (PRI) is a global research and development organization that employs more than 4,300 scientists worldwide. PRI scientists are dedicated to discovering and developing best in class, innovative, therapeutic and preventive agents, with a focus on ten therapeutic areas of significant medical need. Currently, the PRI pipeline comprises more than 50 compounds under active development. In 1999, pharmaceutical research and development spending totaled \$1.4 billion.

For these reasons, we are very interested in and believe that we are qualified to comment on this proposed rule to amend FDA's public information regulations to comply with the requirements of the Electronic Freedom of Information Act Amendments of 1996 (EFOIA).

Summary of BMS Comments on Proposal

We commend FDA for its efforts to comply with EFOIA. We also commend the agency on its efforts to make available other records and information that EFOIA does not require to be made available on the agency's website.

However, there are several aspects of the proposed rule that we believe require change or clarification, which are cited below.

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Specific Comments (Items that Need Clarification & Recommended Actions) Section II, A.

- 1) In section II Proposed New and Revised Provisions (A) 1) b) the proposed rule states that "an agency...should also make reasonable efforts to search for records in their electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems."
 - We recommend that the Agency provide an example of the kind of requests it believes would significantly interfere with the operation of the Agency's automated information systems.
- 2) In Section II, (A) 4) of the proposed rule the Agency indicates that it "is striving toward a common records filing structure that will enhance the agency's ability to respond to requests for records in a particular form of format."
 - We are interested to know if the Agency has requested input from its constituents with regards to a common record filing structure. We recommend that FDA consider comments from all of its constituents to find out what record filing structure would best respond to the requests of the majority of its constituents.
- 3) Under Section II, (A) 10) the agency states that Section 8 of EFOIA (5 U.S.C. 552 (a) (6) (E)) requires agencies to issue regulations 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 rules proposed by FDA would limit situations of "compelling need" primarily to requests made by individuals whose lives or safety are threatened or requests made by the general news media when records are required due to an urgency to inform the public concerning actual or alleged Federal Government activity.
 - Bristol-Myers Squibb is concerned that the scope of those individuals or entities that can demonstrate "compelling need" is too narrow. Pharmaceutical and other healthcare companies, for example, also can be in a position of having to inform the public urgently about FDA regulatory activity. This activity – such as product recalls - often has an impact on the life or safety of individuals. We recommend that the Agency place more emphasis on defining "compelling interest" rather than on limiting the scope of the individuals or entities that are permitted to demonstrate such interest. By unnecessarily limiting the types of parties that can request expedited processing, the Agency may be making artificial distinctions that would deny an individual or entity with a truly compelling interest the opportunity to even raise it without special leave from FDA..

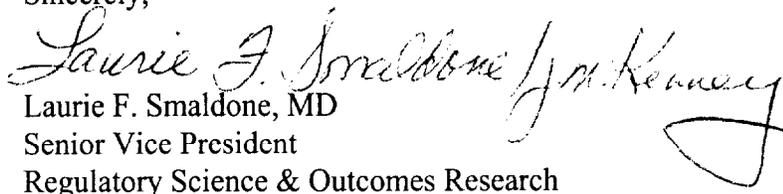
4) In Section II (B) Proposed Changes to FDA's Public Information Regulations Unrelated to EFOIA, Item I Filing a Request for Records, the agency states that it will accept "requests submitted to FOI Staff via facsimile as well as via mail."

- We recommend that, in light of the common use of e-mail in today's business world, e-mail requests also be added as an acceptable means of filing an FOIA request.

BMS appreciates the opportunity to provide comments on the Public Information Regulations pertaining to EFOIA and respectfully requests that FDA give consideration to our comments and recommendations.

We would be pleased to provide additional pertinent information..

Sincerely,


Laurie F. Smaldone, MD
Senior Vice President
Regulatory Science & Outcomes Research