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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 03N-0273
Comment Request - Research Study Complaint Form

Merck & Co., Inc., is a leading worldwide, human health product company. Merck's corporate strategy -- to discover new medicines through breakthrough research -- encourages us to spend more than $3 billion annually on worldwide Research and Development (R & D). Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the important pharmaceutical products on the market today.

Per the Agency's June 30, 2003, *Federal Register* notice soliciting comments on the FDA's burden estimates to use an Internet-based complaint form for public complaints concerning misconduct in research studies, Merck provides the following comments.

1 Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

This collection is not necessary for the proper performance of FDA's functions. As noted in the *Federal Register* notice, FDA currently receives 150 complaints per year related to alleged scientific misconduct in clinical research via E-mail, mail, and personal contacts and will continue to accept complaints via these routes. The current system by which FDA accepts complaints spontaneously appears effective.

An additional route is not needed; Merck discourages the use of an Internet form through which very few complaints may be expected to be filed. It is not clear that Internet collection offers any advantage over existing routes, nor is it clear that it will facilitate the filing of complaints.

2. The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

The Agency estimates it will take respondents one hour to complete the form. This seems reasonable. However, it may take longer for respondents to locate the form on the Internet. It is not obvious on which website(s) the form will reside (e.g. NIH clinical trial sites, HHS website, FDA website) and how easy it will be to locate.

3. Ways to enhance the quality, utility, and clarity of the information to be collected.

Ad hoc reporting of complaints offers a superior collection mechanism because it allows complaining parties to report alleged misconduct without steering the information offered by a form. The existing collections of information via telephone, E-mail, FAX, and mail are proven alternatives.

We discourage the use of the *DSI Complaint Form* as a collection tool; however, should FDA use the form, it should be revised to improve the quality, utility, and clarity of the information to be collected. We offer the following comments for your consideration in the spirit of improving the collection tool:

General Comments:

- The form should provide the FDA with minimal information upon which to investigate a complaint. To this end, the form should be designed to facilitate its completion with readily available information. It may be unlikely that the reporter has the protocol number and full study title readily available.
- The form should be accompanied by an Introduction to the form and how it is to be used.
- The form should be accompanied by Instructions for its completion.
- The form could be improved by reordering the sections so that they appear as: (1) Reporter Information, (2) Complaint description, and (3) Organization about which complaint refers.
- The *Federal Register* notice states, *DSI will contact the complainant if the complainant requests a followup contact.* However, the form lacks this question.

Who Are You Complaining About?

- The form should use terms and explanations easily understood by the lay public at no more than a sixth grade reading level. Terms like "bioequivalence", "sponsor", and "monitor" should be avoided as they are not widely known except by persons associated with pharmaceutical development.

Complaint Information

- *If you know the name(s) of other persons (subjects or staff) who were involved in the study(ies), or who are willing to provide information, please list them.*
  Asking complaining parties to identify other study subjects does not seem consistent with the increased protections being afforded to the privacy of research subjects.
- *How many subjects were enrolled in the study(ies)?*
  While the consent form for a clinical trial should indicate the number of subjects planned for enrollment, it seems unlikely that any one subject would know how many subjects were actually enrolled.

Your Information (optional)

- *If you do not want FDA to know who you are, do not complete this section.* Merck objects to complainants being given the option to report anonymously. Complainants should be willing to identify themselves to FDA and should be assured that their identities will not be disclosed.

4. **Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.**

Although the use of an Internet-based form would appear to simplify the collection of complaints, for the reasons stated above we do not believe the form as currently proposed would do so. The Agency would need to publicize the availability of the form, explain its intent, revise the form's content, and provide instructions for the form's completion in order to make the Internet form a viable addition to existing routes through which complaints are currently captured.

We appreciate the opportunity to comment on this form.

Sincerely,

Lauren M. Hetrick

for David Blois, Ph.D.
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