BIOTECHNOLOGY INDUSTRY ORGANIZATION
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December 17, 2007

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

Re: Docket No. 2007N-0472, OMB control number 0910–NEW, Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) proposed collection of information on the certification to accompany drug, biological product, and device applications or submissions, and also on its draft form for *Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank.* BIO represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

We support FDA's stated goal in providing the form, i.e., to ensure that certain information submitted in compliance with the provisions of Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) is complete and will be provided in a systematic fashion so that it can be more easily retrieved. We are providing the following comments to ensure that the form helps FDA and applicants to achieve this stated goal.

1. Scope of certification requirement

BIO requests clarification of the types of submissions that require an accompanying certification.

a. Exclusion of submissions that do not contain clinical trials. We request explicit clarification that certification is not required for submissions that do not contain clinical trials. We note that option 9A should be removed from the form as it is not necessary.

b. Certification to accompany only new applications. We also request clarification that FDAAA does not require a certification to accompany every drug, biological product, and device submission. Rather, FDAAA only requires certification to accompany a submission of an application under section 505, section 515, or section 520(m) of the Federal Food, Drug, and Cosmetic Act (FDCA) or under section 351 of the Public Health Service Act (PHSA), or a submission of a report under section 510(k) of FDCA. Therefore, FDAAA does not require certification to accompany, for example, supplements or IND submissions.

We note that provision of the certification with every submission would result in substantial unnecessary paperwork for FDA and for applicants.

c. Clarification of which trials trigger the certification requirement. In order for applicants to complete the form (for example, Item 9), it will be necessary for them to understand FDA's interpretation of which trials are subject to the requirements of 42 U.S.C. Sec. 282(j), i.e., "applicable trials." We request that FDA provide guidance concerning the definition of "applicable trials."

d. Request for guidance, and necessity of enforcement discretion until such guidance is provided. Because FDA is unlikely to be able to provide guidance concerning the definition of "applicable trials" prior to December 26 2007, the date when certifications must accompany certain applications and reports, we ask FDA to clarify that it will exercise enforcement discretion with respect to the certification requirement until such guidance is provided.

e. Revision of the Agency Information Collection Activities (AICA) notice. The AICA dated December 12 2007 should be revised in conjunction with the clarifications above, to exclude submissions that do not require an accompanying certification.

2. Revisions to the format of the certification form

a. Item 6 – In accordance with the clarifications requested above, Item 6 should be revised to include only those categories of submissions subject to the requirements of 42 U.S.C. Sec. 282(j), and to include all such relevant categories.

b. Items 9 and 10 – An application or report may reference more than one clinical trial, and some of the clinical trials referenced may be subject to the requirements of 42 U.S.C. Sec. 282(j) while others are not. However, the draft form does not provide for the possibility that an application may contain a combination of clinical trials that are and are not subject to 42 U.S.C. Sec. 282(j). Item 9 should be revised to allow for the possibility that a submission references clinical trials of both types, and item 10 should be revised to

clarify that NCT numbers are only required for those clinical trials subject to the requirements of 42 U.S.C. Sec. 282(j).

c. Item 10 – The instructions for Item 10 of the Form should acknowledge that National Clinical Trial (NCT) numbers will not always be available, for example, if a protocol is not required to be registered.

d. Item 10 - FDA and sponsors use protocol numbers to identify studies, in addition to or rather than NCT numbers. To help avoid confusion, we suggest inclusion of the protocol number along with the NCT number (where it is available) in Item 10.

3. Relationship between the certification and the Common Technical Document (CTD)

We request clarification on how the certification forms should be treated within the CTD. Specifically, how should applicants communicate the cumulative list through time of clinical trials subject to the requirements of 42 U.S.C. Sec. 282(j)?

4. Addition of Perjury Language to Certification

We request removal of the second sentence above the signature block, i.e., "I verify under penalty of perjury that the foregoing is true and correct." FDAAA does not authorize FDA to bring a perjury action for failure to certify accurately.

Conclusion

BIO appreciates this opportunity to provide input to FDA. We look forward to seeing the final certification requirements and form, and would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

Sara Radcliffe
Vice President, Science and Regulatory Affairs

cc: (by fax) Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer