BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

1225 Eye Street NW, Ste. 400
Washington, DC 20005

April 11th, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2005D-0022, Federal Register: February 8, 2005 (Volume 70, Pages 6697-6698)

Dear Sir/Madam:

The following comments are provided by the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO appreciates the opportunity to comment on the Food and Drug Administration's (FDA's, the Agency's) ICH Draft Guidance on S8 Immunotoxicity Studies for Human Pharmaceuticals. The following comments were developed by members of BIO's Preclinical Safety Expert Working Group.

Section 1.3 Scope of the Guideline (lines 101 to 103)

Section 1.3 Scope of the Guideline (lines 101 to 103) currently states: "This guideline is focused on providing recommendations on nonclinical testing for immunosuppression induced by low molecular weight drugs (non-biologicals)".

Comment:

BIO agrees with the intent of this scope and only asks that a sentence similar to the following be added for clarification purposes: "Biotechnology-derived pharmaceuticals (as defined by ICH S6) are not addressed in this guideline and should be evaluated using the general principals of the ICH S6 document".

We believe this clarification is needed due to the fact that the terms "low molecular weight drugs" and "non-biologicals" are open to interpretation and it is best to use definitions already included in other ICH documents (i.e., ICH S6).

In conclusion, BIO appreciates this opportunity to comment on the ICH Draft Guidance on S8 Immunotoxicity Studies for Human Pharmaceuticals. We look forward to seeing the final guidance, and would be glad to work with the Agency to provide further input or clarification of our comments, as needed.

Sincerely,

Sara Radcliffe
Managing Director
Science and Regulatory Affairs