BIOTECHNOLOGY INDUSTRY ORGANIZATION

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February 19, 2008

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2007N-0280, Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals, Companion Document to the Direct Final Rule (Federal Register: December 4, 2007; Volume 72; Number 232; Pages 68113-68116)

Dear Sir/Madam,

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comment on the Food and Drug Administration's (FDA's) *Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals* issued as a direct final rule and its companion proposed rule. 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 innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO thanks FDA for initiating changes to the GMP regulations to provide clarity and to ensure alignment with current industry practices. We also applaud FDA's changes intended to harmonize the GMPs for finished pharmaceutical products with that of other regions. The end result will be valuable to both industry and FDA.

We congratulate FDA on issuing the final rule and we support the changes proposed therein by FDA. We agree that these changes generally provide clarity and consistency with current interpretation and practice. The proposed changes represent a sound initial effort at modernization of the GMP regulations and we look forward to FDA's additional efforts in this area.

Below, we make two suggestions for FDA to consider, one with regard to the proposed requirement to validate aseptic processes and one in regard to the proposed requirement for operator verification of operations conducted using automatic, mechanical and electronic equipment.

- Section 211.133(b) proposes the requirement for validation of aseptic processing with clarification that this is to be demonstrated by process simulation (media fills). We ask FDA to clarify that this "validation" requirement will not inhibit either implementation of ICH Q8, 9 and 10 employing novel technologies or other innovative approaches in these areas.

- Automated, validated systems equipped with real time alarms that do not require any human intervention should not require human verification. The proposed revision requiring operator verification of automatic mechanical and electronic equipment in sections 211.68(c), 211.101(c)(3), 211.101(d), 211.103, and 211.188(b)(11) may hinder the implementation of process analytical technology (PAT) within the pharmaceutical industry.

Finally, for all changes, we note that it will be very important for FDA to ensure clarity and consistency in understanding of the final rule among FDA staff, including both product reviewers and GMP inspectors, in order to minimize different interpretations and application of these regulations across the agency.

Thank you again for the opportunity to comment. We would be pleased to provide further input or clarification of our comments, as needed.

Regards,

/s/

Sara Radcliffe
Vice President, Science and Regulatory Affairs
Biotechnology Industry Organization