SOCMA
SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION

October 1, 2003

Via Facsimile and Mail

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

Re: Docket Nos. 2003D-0060; Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures -- Scope and Application;" Availability.

Dear Sir or Madam:

The Bulk Pharmaceutical Task Force (BPTF) of the Synthetic Organic Chemical Manufacturers Association (SOCMA) appreciates the opportunity to provide comments on the Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures – Scope and Application." BPTF is committed to aiding in the promotion of public health and would like to work closely with the Food and Drug Administration (FDA) as it develops regulations and guidance materials for Part 11.

We would like to begin by introducing our organization to FDA. BPTF is an association for manufacturers of active pharmaceutical ingredients (APIs), excipients, and intermediates committed to excellence in cGMP compliance and regulatory solutions. One of our primary goals is to seek clarification of the status and treatment of APIs, which is often uncertain under current regulation and policy. The Task Force coordinates these efforts on behalf of SOCMA, the leading trade association of the specialty-batch and custom chemical industry. The association represents 300 member companies with more than 2,000 manufacturing sites and 100,000 employees. The membership includes representatives from each segment of the industry – from small specialty producers to large multinational corporations.

The following comments are submitted in response to the publication of the Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures – Scope and Application." BPTF welcomes this guidance on the scope and application of Part 11 and strongly supports FDA's utilization of a risk-based approach to compliance. The risk-based approach is a reasonable and effective way to protect the public health. It will allow industry to review correlated risks and assign appropriate priorities in order to focus its attention on the most critical issues.

BPTF is especially supportive of the revision and clarification of the scope of Part 11 as applicable "to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations." The Guideline clarifies that FDA will interpret Part 11 narrowly, and thus, bring fewer records under the Part 11 requirements. Historically, Part 11 was interpreted broadly and had included any record captured in electronic format. The system was unwieldy, confusing, and often seen as creating unnecessary controls and costs. In addition, it generally impeded technological innovation due to the more onerous requirements for electronic records.

Under the narrow interpretation, Part 11 would apply to records FDA mandates that industry maintain or submit only when one *chooses* to use records in an electronic format in place of the paper format. The merely incidental use of computers, such as when one simply uses computers to generate paper printouts of electronic records or when one relies on paper records to perform regulated activities, would not trigger Part 11. The paper record would meet all FDA's requirements. As stated in the guidance document, FDA would not consider these instances to be "using electronic records in lieu of paper records" under §§11.2(a) and 11.2(b). This clarification will provide FDA with a rational basis from which to develop the specific Part 11 requirements.

As stated in 21 C.F.R. §11.1(b) and reaffirmed several times in the Guidance, Part 11 is applicable only to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in Agency regulations, the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act. Thus, in order to be subject to the Part 11 requirements, one must first be subject to a predicate regulation for recordkeeping.

The products provided by the bulk pharmaceutical industry are not explicitly covered by any such Agency regulation or statute pertaining to records, i.e., provisions in the Current Good Manufacturing Practice regulations for finished pharmaceuticals (21 C.F.R. Part 211). Rather, the reporting requirements for our industry is guided by the August 2001 Guidance for Industry, "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients." This document, based on standards developed by the International Conference on Harminisation, provides guidance on good manufacturing practices for the manufacture of active pharmaceutical ingredients under an appropriate system for managing quality. It is intended to ensure that APIs meet the quality and purity characteristics they are supposed to possess.

As guidance, however, it does not reach the level of a regulation and only represents the FDA's current thinking on the topic. Because it does not rise to the level of regulation, it cannot bring actives and excipients under the ambit of the Part 11 requirements. While the Part 11 regulations and, therefore this Guidance on Part 11, are not specifically applicable to API and excipient manufacturers, BPTF has an interest in it and the re-examination of Part 11 as manufacturers of finished pharmaceuticals sometimes require their bulk suppliers to adhere to

the finished pharmaceutical requirements. Therefore, the more clarity FDA provides to pharmaceutical manufacturers, the easier it is for active ingredients and excipient manufacturers to meet their customer's expectations.

We believe that the use of enforcement discretion for certain requirements of Part 11 during the review is a logical interim measure for the period during which FDA will re-examine Part 11 as applied to validation, audit trail, record retention, and record copying. While industry must still fastidiously maintain these records, the interim relief will help minimize the amount of confusion associated with changing the Part 11 requirements.

BPTF recognizes that integrating the risk-based processes into the specific Part 11 requirements for validation, audit trails, and electronic data retention will take time and substantial effort. BPTF encourages FDA to provide, and BPTF stands ready to assist FDA, further guidance for bulk manufacturers as to how appropriate concepts embodied in a risk-based approach to electronic records would apply to bulk pharmaceuticals.

BPTF strongly feels that FDA should consider the unique perspective of the API and intermediates industry as part of issuing guidance related to its re-examination of Part 11. The depth and expertise of this industry sector are vital components of the U.S. chemical industry and contribute significantly to U.S. global competitiveness.

Once again, BPTF appreciates the opportunity to comment on the Guidance document. We look forward to continuing to work with FDA in the development of standards for Part 11.

Sincerely,

Alan Nicholls, Chairman
Bulk Pharmaceutical Task Force