GME
GELATIN MANUFACTURERS OF EUROPE

25 June 2003
MVE/mcv/465/cor/03-162

Food and Drug Administration
Docket Management Branch
HFA –
5630 Fishers Lane – Room 1061
Rockville MD 20582
USA

Attention : Docket N° 02N-0277

RE BIO TERRORISM ACT
SECTION 306 (MAINTENANCE OF RECORDS)

Dear Sirs,

The Gelatin Manufacturers of Europe (GME) represents 9 European companies with a total of 18 production plants and accounts for 45% of worldwide gelatine production and as such we would like to comment on the above proposed Regulation for Registration of Food Facilities.

We thank you in advance for your clarifications and hope you will take our comments into consideration.

Yours sincerely

Marc Vermeulen

Appendix (Comments on Section 306)

02N-0277 C104

GME

GENERIC MANUFACTURERS OF EUROPE

Bio-terrorism Act - Section 306

Establishement and Maintenance of Records

1. **Chapter I.A „Background" (page 5):**

   In the detention document the FDA takes action when an officer or qualified employee of FDA has "credible evidence" (defined as "trustworthy") that an article presents a threat. In this recordkeeping document a "reasonable belief" is already sufficient for action. For safety reasons FDA should not simply rely on a belief of an officer but on evidence found during an inspection, examination, or investigation. GME is of the opinion that it would be better to bring the requirements closer together for both the detention document and the recordkeeping document.

2. **Chapter I.B „Stakeholder Comments" (page 7):**

   GME supports that there is no need to specify the form or manner in which the information must be kept. Additionally, it is important that the regulations provide flexibility for using existing recordkeeping systems.

3. **Chapter I.C „Highlights" (page 11) and II. E.s (page 46):**

   In case of a reasonable belief that a food is adulterated, it is necessary to provide records of the "previous source" and the "subsequent recipient" for nontransporters, transporters and to trace the transportation process within 4 respectively 8 hours. This is a lot of paperwork. Due to the time shift between USA and EU, it may sometimes be difficult to contact the persons (transporters/nontransporters) of the previous source and to receive the necessary records/documents within the timeframe of 4 respectively 8 hours. GME thinks that it would be easier for the FDA officers to contact immediately the US agent, who should already have all the necessary documents available. Otherwise, he should take care to provide them as soon as possible. It is the understanding of the GME that the office of the US agent would as well be a "reasonable accessible location" (II. E.1, page 45) where all records can be collected and stored. If this is not possible, alternatively the timeframe could be extended to e.g. 24 hours for foreign facilities.
