European Federation of
Pharmaceutical Industries
and Associations

Fédération Européenne
d'Associations et d'Industries
Pharmaceutiques

Ref: SC.sr/58.556 **October 29th, 2003**

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

Dear Sir/Madam,

Re: EFPIA Comments on Draft Guidance for Industry on Providing Regulatory Submissions in electronic Format – Human Pharmaceutical Product Applications and Related Submissions [Docket No 2003D-0367]

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Its mission is to promote pharmaceutical research and development in Europe. Founded in 1978, its members consist of 18 national pharmaceutical industry associations and 43 pharmaceutical companies involved in the research, development and manufacturing of medicines for human use. Our membership also includes national industry associations in the acceding countries, i.e. the 10 countries which will join the European Union as from May 2004.

The comments submitted in this document have been written by EFPIA Product and Regulatory Information Management Ad Hoc Group (PRIMAG AHG).

EFPIA welcomes the opportunity to comment and appreciates the effort that has gone into the definition of the guidance and associated specifications. However, there are several areas of significant concern and many areas where specific detail is lacking and clarification is needed. These are detailed in the attached document.

We thank you in advance for giving due consideration to our comments.

Yours faithfully,

Stéphane Callewaert
Scientific, Technical and Regulatory Affairs

Encl.: EFPIA comments

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