



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 22, 2002

William W. Bradley
Chairman, Steering Committee
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036-4193

Dear Mr. Bradley:

Thank you very much for your December 19, 2001 letter on behalf of the Industry Coalition on 21 C.F.R. Part 11. In your letter, the Industry Coalition requests a ninety (90) day extension for the submission of comments to the Food and Drug Administration's (FDA) dockets relating to the draft Guidances for Industry 21 C.F.R. Part 11; Electronic Records; Electronic Signatures Validation and Glossary of Terms. This letter serves as FDA's response to the Industry Coalition's request.

The agency acknowledges that many federal agencies, including the FDA have developed documents that relate to the concept of validation and the terms in the proposed glossary. The agency also recognizes, to the extent that it is possible, that the Part 11 guidance documents should be consistent with the above-mentioned documents. Therefore, FDA is eager to receive complete, thoughtful, and meaningful comments as a part of the agency's effort to develop and issue guidance documents relating to 21 C.F.R. Part 11.

The original comment period for the draft Guidances for Industry 21 C.F.R. Part 11; Electronic Records; Electronic Signatures Validation and Glossary of Terms was 90 days. Pursuant to 21 C.F.R. 10.115(g)(5), however, the Industry Coalition and other commenters "can comment on any guidance document at any time." Therefore, despite the fact that the comment period closed on December 24, 2001, FDA does not intend to deviate from the good guidance practice regulations and the agency will continue to accept comments from the Coalition and other commenters in accordance with the regulations.

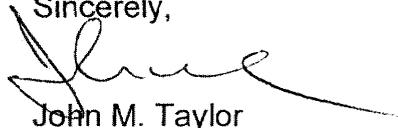
However, in light of the original 90-day comment period and the importance of finalizing the guidance documents described above, the agency does not intend to suspend its efforts in working towards finalizing the draft guidance documents.

OOD-1538

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Consequently, even though FDA will consider comments submitted after December 24th by the Industry Coalition and other commenters, the agency does not intend to grant any formal extensions to the 90-day comment period.

Sincerely,



John M. Taylor
Director
Office of Enforcement

cc: Sonal Vaid, Esq.
Paul Motise
Docket Management
Docket No. OOD-1538
Docket No. OOD-1543

Industry Coalition on 21 CFR Part 11

Consumer Healthcare Products Association
Pharmaceutical Research and Manufacturers of America
National Food Processors Association
Cosmetic, Toiletry, and Fragrance Association
Advanced Medical Technology Association
Generic Pharmaceutical Association
Council for Responsible Nutrition
Animal Health Institute
Medical Device Manufacturers Association
National Electrical Manufacturers Association
Council on Radionuclides and Radiopharmaceuticals

December 19, 2001

John M. Taylor
Director, Office of Enforcement (HFC-200)
Office of Regulatory Affairs
Food and Drug Administration
1350 Piccard Drive
Rockville, MD 20850

Re: **Docket No. OOD-1538**
Guidance for Industry 21 CFR
Part 11; Electronic Records;
Electronic Signatures
Validation

Docket No. OOD-1543
Guidance for Industry 21 CFR
Part 11; Electronic Records;
Electronic Signatures
Glossary of Terms

Dear Mr. Taylor:

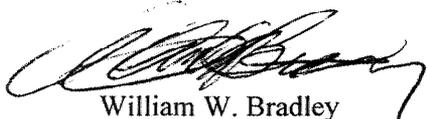
The Industry Coalition on 21 CFR Part 11 has been reviewing the draft *Guidances for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Validation* and *Glossary of Terms*. Based upon input from the member organizations, we respectfully request a 90-day extension of the December 24, 2001 deadline for submittal of comments to this draft guidance.

As these are the first Part 11 guidance documents released for review, they have generated many complex questions and discussion points. The Coalition has been working to consolidate these comments and to coordinate them in light of current practices and available information. This has been a challenging task due to the many complex comments received from members. The Coalition working group has found that many existing documents and guidances, many of them developed by various federal agencies including FDA, address the issues of validation and glossaries of terms. We believe that the Part 11 guidances should be consistent with these existing documents, where possible. In any case, these documents need to be reviewed and considered with the subject draft guidances.

This leads us to conclude that fair and meaningful comments on these draft guidances will require additional time. We believe that the additional time will allow for the most thoughtful and helpful comments to be submitted, and will be beneficial to both the agency and the industry.

We look forward to your favorable consideration of this request.

Sincerely,


William W. Bradley
Chairman, Steering Committee