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June 25, 2003

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

RE: Docket No. 02D-0526: Draft Guidance for Industry on Drug Product: Chemistry, Manufacturing, and Controls Information; Availability

Dear Sir or Madam:

Amersham Health, Inc. has reviewed the referenced draft guidance for industry and is grateful for the opportunity to provide our comments. Our comments to Docket No. 02D-0526 are provided on the following pages.

These comments are being provided in duplicate in written form and electronically as directed in the Federal Register Notice.

If you have any questions, please contact me at (609) 514-6427 or at e-mail: michael.barbush@amersham.com.

Sincerely,

Amersham Health, Inc.

Michael Barbush
Senior Manager
Regulatory Affairs

Comments to Docket No. 02D-0526

General Comments:

1. Where appropriate, provide a correlation table matching the old NDA format to the new CTD format. This helps to place the information in the old format into the correct section in the CTD format.

2. Delete section classifications III, IV, V, VI, VII, VIII, IX, X, XI, XII, XIII and replace with P1, P2, P3, P4, P5, P6, P7, P8, A, and R, respectively. For example, use "P.2 PHARMACEUTICAL DEVELOPMENT" instead of "IV PHARMACEUTICAL DEVELOPMENT (P.2)." This will allow the document to be consistent with CTD section names and numbers.

Specific Comments:

1. Section IV-C (P.2.3); Lines 580-582: The statement can be extended to include: ".... if differences in the equipments used in the various phases could have impact on quality, safety and efficacy".

2. Section IV-D (P.2.4); Lines 596-597: The statement needs to be explicit with regard to other (non-protein) drug products.

3. Section V-C (P.3.3); Lines 808-809: The meaning of 'equipment identify by type' should have a more extensive explanation.

4. Section VI-A (P.4)/(P.4.1); Lines 996-1011: There is no need to provide information in P4.6 that is given in A.3. Cross reference to A.3 should be sufficient.

5. Section VII-A (P.5.1); Line 1176: Provide the definition of Periodic Quality Indicator Test in the Glossary.

6. Section VII-A (P.5.1); Lines 1187-1189: The sentence "A PQIT can be warranted when a test, performed and reported as part of the batch analyses, has value as an indicator of product quality, but information indicates that the test need not to be performed on each batch of drug product" is somewhat ambiguous and should be re-written.

7. Section VII-A (P.5.1); Lines 1212-1215: Should not an Out of Specification (OOS) investigation for a PQIT be resolved <u>before</u> any new production of batches?

8. Section VII-A (P.5.1); Line1216: Delete the word "all" from the sentence.

9. Section VII-A (P.5.1); Lines 1223-1224: This sentence should be revised by adding the following text (underlined here): "A list of PQITs.....should be included in P.5.1 of the application, <u>listed separately from drug product regulatory release specifications.</u>" This will help differentiate the product's release specifications from the product's PQIT specifications.

10. Section VII-D (P.5.4); Lines 1288-1291: With regard to batch analysis information, if not used for the stated purpose, does this mean preclinical/ toxicological batch need not be included in batch tables?

11. Section VII-D (P.5.4); Lines 1288-1309: An illustrative example of a batch analysis table would be beneficial. The illustrative examples of a composition statement (Table 1), a batch formula (Table 2), and a specification sheet (Table 3) provided in the respective sections of the guidance are informative. A similar illustrative example of a batch analysis table in section P.5.4 could be useful.

12. Section VII D (P.5.4); Lines 1328-1339: Collated batch analyses data should be provided in P.5.6 as part of the justification for determining proposed acceptance criteria for the drug product.

13. Section VII-F (P.5.6); Line 1457: The definition for the Sunset test protocol should be provided in the Glossary.

14. Section VII-F (P.5.6); Line 1480: The definition for the Interim acceptance criteria should be provided in the Glossary.