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November 22, 2000

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

1990 '00 NOV 24 AM 10:55

**Re: (Docket No. 00D-1424) Draft Guidance for Industry on Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation**

Eli Lilly and Company is pleased to have the opportunity to comment on the subject draft guidance. We applaud FDA's efforts to provide guidance with respect to analytical procedures and methods validation.

To further assist the FDA in the development of the draft guidance, please find attached Eli Lilly and Company's major comments and a set of detailed comments with rationale on a line by line basis for the draft guidance issued July 19, 2000.

We wish to emphasize and request that the FDA Guidance:

- 1) be consistent with the current ICH guidances. The FDA Guidance should reference the appropriate ICH guidance, rather than repeating its content.
- 2) not require regulatory analytical procedures to contain additional level of detail beyond that required in the USP monograph. An increased level of detail beyond that in the USP/NF is contrary to the principles of PDUFA as it creates an increased regulatory burden when only minor changes are made to the analytical procedure. Though auxiliary information should be provided to the FDA, we recommend that regulatory analytical procedures contain the same level of detail as given in USP monographs.

Please feel free to contact me at (317) 433-9882 for clarification of any comments.

Sincerely,

Diane Zezza, PhD.  
Director, Global Regulatory Affairs,  
Chemistry Manufacturing and Control

cc: Alfred Del Grosso, Ph.D., CBER  
Eric Scheinin, Ph.D., CDER

Radhika Rajagopalan, Ph.D., CDER  
Robert Yetter, Ph.D., CBER

00D-1424

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**Eli Lilly and Company Comments on:  
Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)  
Major Comments**

Level of Detail in Regulatory Analytical Procedures

In numerous places, the Guidance requires detail in regulatory analytical procedures not required in USP monographs. This level of detail is inappropriate in the registration and should be removed from the guidance for the following reasons.

1. The analytical procedures in the USP/NF are legally recognized under section 501(b) of the Act as regulatory analytical procedures.
2. According to USP <1225>, the analytical procedure in the USP/NF “should contain a complete description of the analytical method sufficiently detailed to enable persons ‘skilled in the art’ to replicate it”.

We recommend that at a minimum the regulatory analytical procedure contain the same level of detail described in a USP monograph method. Changes in the regulatory analytical procedure would be reported in accordance with FDA’s Guidance “Changes to an Approved NDA or ANDA” (November 1999).

To aid the FDA Laboratories in performing the analytical procedure, we recommend that an auxiliary sheet with more detailed instructions be submitted with method validation samples. The auxiliary sheet would include such information as the specific chromatographic columns found suitable for the method. The information in this auxiliary sheet would not be updated.

The table below lists the information that should be omitted from the guidance.

Section	Lines	Item
VI. Content and Format of Analytical Procedures	196-198	<p>“The number of samples selected...” and “...the number of replicate analyses per sample should be described.”</p> <p><u>Note:</u> The USP General Notices states “ Tests and assays in this Pharmacopeia prescribe operation of a singlet determination which is the minimum sample on which the attribute should be measured. Some tests, such as those for <i>Dissolution</i> and <i>Uniformity of dosage units</i>, require multiple dosage units in conjunction with a decision scheme. ... These procedures should not be confused with statistical sampling plans. Repeats, replicates, statistical rejection of outliers, or extrapolations of results to larger populations are neither specified nor proscribed by the compendia; such decisions are dependent on the objectives of the testing.” (USP 24, page 10) To be consistent with the USP the regulatory analytical procedure should describe the testing of a singlet. Description of a statistical sampling plan, as suggested by the above text, is out of the scope of this guidance.</p>

Level of Detail in Regulatory Analytical Procedures: Information that should be omitted from the guidance (Continued)

Section	Lines	Item
VI. Content and Format of Analytical Procedures	249-250	<p>Specific number of significant digits to report</p> <p>Note: The USP General Notices states that “an observed or calculated results is to be rounded off to the number of places that is in agreement with the limit expression.” (USP 24, page 4)</p> <p>Proposed text:</p> <p>The units of measure used to report results (e.g., percent label claim, weight/weight percent, weight/volume percent, parts per million (ppm)) should be included in the procedure. The number of significant figures to be reported are designated by the significant figures in the acceptance criteria.</p>
VII. Methods Validation	309-310	<p>Representative calculations using submitted raw data, to show how the impurities in the drug substance are calculated.</p> <p>Rationale: The procedure includes where necessary the formula and definition of terms needed to perform calculations. A representative calculation should not be needed.</p>
XI. Methodology	661-677	<p>The following items for HPLC columns:</p> <ul style="list-style-type: none"> <li>• Commercial supplier (listed in the Pharmacopoeial Forum proposal, but not in the USP monograph)</li> <li>• Frit size</li> <li>• Filter type</li> <li>• Precolumn and/or guard column type, if used</li> <li>• Particle shape and pore diameter</li> <li>• Surface modification</li> <li>• Recommended pH range for column use</li> </ul>
XI.	701-710	<p>The following HPLC operating parameters</p> <ul style="list-style-type: none"> <li>• Sequence of Injection of blanks, system suitability standards, other standards, and samples</li> <li>• Order of addition of reagents when preparing the mobile phase</li> <li>• Methods of filtering and degassing the mobile phase</li> <li>• Rationale for the use of precolumns and/or guard columns</li> </ul>
XI.	714-729	<p>The following items for GC columns:</p> <ul style="list-style-type: none"> <li>• Commercial supplier</li> <li>• Column conditioning procedure</li> <li>• Purity and pressure of gasses</li> </ul> <p>For glass-packed GC columns the specific length, internal diameter, and external diameter will vary slightly with the model of the GC unit.</p>
XI.	763-782	<p>The following items for Capillary Electrophoresis, Operating Parameters:</p> <ul style="list-style-type: none"> <li>• Order of addition of the components of the running buffer</li> <li>• Model of CE equipment used</li> </ul>

### Location of Information within the Application

The analytical procedures are linked to information provided in other sections of the application; however, the location of information within the application is not clearly defined in the Guidance. The draft Guidance seems to contradict the FDA Guideline "Format and Content of the Chemistry, Manufacturing, and Controls Section of an Application" (February 1987). The draft Guidance implies that certain types of information should be included in either the analytical procedure or method validation even though the current guideline on Format and Content provides other sections for the information. The guidance for Analytical Procedures and Method Validation should be consistent with the existing guideline for Format and Content. The location of information specified in the Format and Content guideline should be maintained.

The following outline gives the structure of the drug substance portion of the application according to the Guideline on Format and Content.

#### **Structure of the Drug Substance Portion of the Application**

- I. Drug Substance
  - A. Description, Including Physical and Chemical Characteristics and Stability
    - 1. Names
    - 2. Structural Formula
    - 3. Physical and chemical characteristics
    - 4. Elucidation of structure
    - 5. Stability
  - B. Manufacturer(s)
  - C. Method(s) of Manufacture and Packaging
    - 1. Process controls
    - 2. Container closure system
  - D. Specifications and Analytical Methods for the Drug Substance
  - E. Solid-State Drug Substance Forms and Their Relationship to Bioavailability

The following table describes the information for which the FDA Guideline on Format and Content of the CMC Section specifies a section but that the Guidance on Analytical Procedures and Method Validation implies should be included in Section I.D. Specifications and Analytical Methods in the analytical procedure or method validation.

Information	Guidance on Analytical Procedures and Method Validation	Location according to Guidance on Format and Content on CMC Section
Chemical attribute information such as structural formula, empirical formula, and molecular weight	lines 134-135, line 898	I.A.2. Structural Formula
Information to substantiate the proof of structure . . .	lines 135-140, line 898	I.A.4. Elucidation of Structure
A physical description of the material, including its color and physical form.  Appropriate physical constants such as melting range, boiling range, refractive index, dissociation constants (pK values), and optical rotation.	lines 141-143, line 898	I.A.3. Physical and Chemical Characteristics
Information from stress studies (see section VII.A.2.b).	line 311*, lines 901 and 912	I.A.5. Stability
Discussion of the possible formation and control of polymorphic and enantiomeric substances	lines 315-316*	I.E. Solid State Drug Substance Forms (polymorphs)  I.C. Method of Manufacture (enantiomers and polymorphs)
Control of inorganic impurities and residual solvents	lines 319-320*	I.D. Specifications and Analytical Methods (as part of the rationale for specifications)
The analytical procedure number, batch number, manufacturing date and site, and date of analysis should be provided.	lines 390-391*	I.D. Specifications and Analytical Methods (as part of the tabulation of the impurity content of all batches of the new drug substance used for clinical, safety, and stability testing, as well as for batches representative of the proposed commercial process)

\*Draft guidance suggests this information should be included as part of the method validation package.

**Eli Lilly and Company Comments on:  
Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)  
Detailed Comments**

Section	Lines	Comment	Rationale
I. Introduction	22-26	Delete lines 22-26:  Although this guidance does not specifically address the submission of analytical procedures and validation data for raw materials, intermediates, excipients, container closure components, and other materials used in the production of drug substances and drug products, validated methods analytical procedures should be used to analyze these materials.	This statement is out of the scope of the guidance. As stated in lines 2-4 the scope of this guidance is “analytical procedures, validation data, and samples to support the documentation of identity, strength, quality, purity, and potency of drug substances and drug products.” Also see comment for line 62.
II. Background	62	Please change the statement,  From: “All analytical procedures are of equal importance from a validation perspective.”  To: “All analytical procedures must be validated to the degree that is appropriate for the intended use.”	The intent of this statement needs to be clarified. All analytical procedures must be validated; however, the extent of validation must be appropriate for the intended use of the procedure. For example, validation required for the potency assay of the drug substance or drug product would be significantly different than that required for an in-process test.
II.	64-65	Please change the sentence to:  Quantitative procedures should be designed to achieve precision appropriate for the intended use.	
III. Types of Analytical Procedures	78	Please add the following sentence after line 78:  Regulatory analytical procedures include both USP/NF analytical procedures for compendial items as well as procedures in the approved NDA or ANDA.	Please clarify the definition of a regulatory analytical procedure. It should include both USP/NF analytical procedures for compendial items as well as methods in the approved NDA or ANDA.

**Draft FDA Guidance "Analytical Procedures and Methods Validation" (Docket No. 00D-1424)  
Detailed Comments (continued)**

Section	Lines	Comment	Rationale
IV. Reference Standards	102-103; 107-108; 112	<p>Please change lines 102-103 to read as follows:</p> <p>When there is no official source, a reference standard for the active moiety should be of the highest possible purity and be fully characterized. Other reference standards should be characterized as appropriate for their intended use.</p> <p>Please change lines 107-108 to read as follows:</p> <p>If a reference standard for the active moiety is from a non-official source, a certificate of analysis should be submitted in the section of the application on analytical procedures and controls.</p> <p>Please change line 112 to read as follows:</p> <p>C. Characterization of a Reference Standard for the Active Moiety</p>	<p>Different types of reference standards (RS) are used to characterize the active ingredient and drug product. For example, there are standards for the active moiety itself, for residual solvents, and for general tests such as endotoxins. The Guidance does not distinguish between these different types of reference standards.</p> <p>RS for tests such as residual solvents or counter-ion identity are typically reagent grade materials and are not characterized to the same extent as drug substance RS. Depending upon the intended use (peak identity only versus quantitation), it may not be necessary to prepare RS for impurities to the same degree of purity as those for the drug substance.</p>
IV.	116-120	<p>Please change lines 116-120 to read:</p> <p>The qualitative and quantitative analytical procedures used to characterize a reference standard are expected to be <del>different from, and</del> more extensive than, those used to control the identity, strength, quality, purity, and potency of the drug substance or the drug product.</p>	<p>Though it is generally expected that additional tests will be necessary for characterization of the reference standards, some tests used for control of the drug substance or drug product may also be suitable for characterization of the reference standard. If such analytical procedures are suitable it is not reasonable to require new analytical procedures to be developed.</p>
VI. Content and Format of Analytical Procedures	182-187	<p>Please provide a list of FDA recognized standard references as an appendix to the Guidance.</p>	<p>The applicant needs to know when a reference to an analytical procedure is appropriate and when a copy of the method is required.</p>
VI.	210-212	<p>Please change lines 210-212 to read:</p> <p>Chemically unstable and potentially hazardous reagents should be identified.</p>	<p>Details related to chemical properties should not be repeated within the analytical procedure. It is the expectation in the chemical industry to provide and reference MSDS for this information.</p>

**Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)  
Detailed Comments (continued)**

Section	Lines	Comment	Rationale
VI. Content and Format of Analytical Procedures	226-228	Please delete the statement: For example, titration analytical procedures should always include the evaluation of a blank (commonly referred to as a <i>blank titration</i> ).	It is agreed that blanks should be part of a titration procedure, however, this is an inappropriate example. The absence of a response or the measuring of a baseline response in the absence of a sample (a blank) does not adequately ensure the system will respond appropriately to the analyte of interest.
VI.	252-255	Please change lines 252-255 as follows: Chromatographic procedures for organic impurities in the drug substance and drug product should describe the identification of specified impurities (e.g. retention time, relative retention time).	Only individually specified impurities need to be included explicitly in the procedure. Information on other impurities is included in the method validation. Whether the specified impurity is a process impurity or degradation product is immaterial in the analytical procedure section.
VI	256-257	Information on how to determine the detection or quantitation limit should be moved to the method validation section.	This information describes how to validate an analytical procedure.
VI.	260-262	Please change lines 260-262 as follows: The total organic impurities for the drug product or drug substance is the sum of all impurities greater than the reporting threshold as defined in ICH Q3A(R) and Q3B(R).	FDA guidances must be consistent with ICH. ICH Q3A(R) Step 2 and Q3B(R) Step 2, state “All impurities at a level greater than (>) the reporting threshold should be summed and reported as Total Impurities.”
VI.	263-264	Please delete the following sentence: Inorganic impurities and residual solvents should also be addressed.	ICH Q3A and Q3C already address the need to consider inorganic impurities and residual solvents. This information does not belong in the section on how to report impurity results.
VII. Method validation	309-310	Please delete lines 309-310.	The procedure includes where necessary the formula and definition of terms needed to perform calculations. A representative calculation should not be needed.

**Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)**  
**Detailed Comments (continued)**

Section	Lines	Comment	Rationale
VII. Method validation	311	Please delete line 311.	Though information from stress testing may be relevant to method validation to demonstrate the stability-indicating nature of the method, the details of these studies are described in the Stability section of the application and do not belong in the method validation.
VII.	315-316	Please delete lines 315-316	Possible formation and control of polymorphic and enantiomeric substances is discussed elsewhere in the application. I.E. Solid State Drug Substance Forms (polymorphs) I.C. Method of Manufacture (enantiomers and polymorphs)
VII.	317-325	Please delete lines 317-325.	Specificity with respect to the identification of impurities is discussed in ICH Q2A and Q2B. These guidelines should simply be referenced instead. It should also be noted that the requested information in lines 317-320 and lines 324-325 are discussed elsewhere in the application.
VII.	340-341	Please delete the following sentence: In cases where an effect is observed, representative instrument output (e.g. chromatograms) should be submitted.	Results of the robustness study should be discussed, but it does not need to include chromatograms.
VII.	342-355	Please delete lines 342-355.	Separating the discussion about the design of the stress studies and the results, which may include chromatograms, will not facilitate understanding. Though the stability indicating nature of the analytical procedure may be discussed in the method validation, the design and results of stress studies should be presented in the Stability section of the application.

**Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)  
Detailed Comments (continued)**

Section	Lines	Comment	Rationale
VII. Method validation	349-350	If this section is retained, please change lines 349-350 as follows: Stress studies are described in ICH Q1A and Q1B.	The guidance should acknowledge existing ICH guidance.
VII.	352-355	If this section is retained, please change lines 352-355 as follows: For the organic impurity test, stress degradation products should be considered in determining the specificity of the analytical procedure.	This statement will provide greater clarity about the information to be submitted and where to place it in the application.
VII,	356-414	Section VII.A.2.c., please change the title from “Instrument Output/Raw Data” to “Data Summary” and remove from the text specific references to “raw data”.	Though the attributes mentioned in this section need to be discussed in the application, the request for raw data is inappropriate. Allowance should be made for discussing the information in summary form. The raw data is available for inspection, and does not need to be included in the application.
VII.	364-369	Please delete lines 364-369, beginning with “Additional information . . .”	Though it is understood the intent is to provide an example, the example given implies an approach that is not very thorough in confirming that the impurity profile is adequately characterized.
VII.	379-383	If lines 252-355 are retained, please delete the following sentence: Data should be submitted showing the separation and detection of impurities using spiked or stress samples.	This statement is redundant with lines 352-355.
VII.	387-388	Please change the sentence in lines 387- 388 as follows, “The analytical procedure should be capable of differentiating changes, if any, between past and present batches made by the same manufacturing process.”	A given analytical procedure should be able to differentiate changes between past and present lots made by the same manufacturing process. It must be recognized that when a manufacturing process is changed, a different analytical procedure may be required for a complete evaluation of the change.

**Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)  
Detailed Comments (continued)**

Section	Lines	Comment	Rationale
VII. Method validation	401-410	Please delete lines 401-410.	This is a new requirement representing an increase in regulatory burden. Instrument output and raw data should not be a submission requirement. The raw data are available for inspection and do not need to be included in the application.
VII.	426-448	The ICH Q2A includes this information and should be referenced rather than repeated in the guidance. If FDA chooses to retain the table, please delete the column “Specific Tests”	It would be preferable that FDA guidance documents simply reference ICH guidances. The column “Specific Tests” represents a new class of tests not defined in the ICH Q2A table.
VII.	434	Please revise the footnotes to be consistent with ICH Q2A.	It would be preferable that FDA guidance documents simply reference ICH guidances. If information is repeated it must be consistent with the ICH document.
VII.	439	Please delete the row “Robustness” from the table.	Robustness is not included in the table in ICH Q2A.
VII.	452-459	Please delete the following sentences: A specific identification test should be included for the active ingredient whenever possible. In cases where a nonspecific identification analytical procedure is proposed for the active ingredient, two independent analytical procedures are generally sufficient, if justified. For other identification tests (e.g. a chiral HPLC retention time as confirmation for the presence of an enantiomer, chloride test for a counterion) a single test is acceptable. This concept of the number of identification tests is applicable to both the drug substance and drug product.	This section describes how to choose an identification test, but not how to validate one. This information is already provided in ICH Q6A.
VII.	471-478	Please delete the section “Specific Tests”.	Deletion of this section is consistent with deletion of the column “Specific Tests” from the table in lines 427-439.
VIII. Statistical Analysis	496-500	Delete the lines 496-500 beginning with , “The statistical procedures in the analysis of the validation data . . . “	Acceptability criteria may not be known since capability of the method may determine how it will be used. Acceptance criteria ranges are usually set based on method capability, not the other way around.

**Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)  
Detailed Comments (continued)**

Section	Lines	Comment	Rationale
VIII. Statistical Analysis	501-502	Please delete the following sentence: The raw methods validation data and statistical procedures used to analyze the raw data should be provided and discussed in the sections on analytical procedures and controls.	The raw data are available for inspection and do not need to be included in the application.
VIII.	505-513	“Comparative Studies” should be “Intermediate Precision and Reproducibility” in the title and within the text of the paragraph.	The terms intermediate precision and reproducibility are defined in ICH and seem to be more consistent with the intent of the section; whereas, comparative studies could be interpreted to imply the comparison of different methods.
XI. Methodology	677	Please delete line 677.	Unless the packing material requires special precautions due to the conditions specified in the analytical procedure, the pH range does not need to be specified.
XI.	681-689	Please delete the following sentence: The system suitability tests listed below are defined in CDERs reviewer guidance on Validation of Chromatographic Methods (November 1994) <ul style="list-style-type: none"> <li>• Tailing factor</li> <li>• Relative retention</li> <li>• Resolution</li> <li>• Relative standard deviation (RSD)</li> <li>• Capacity factor</li> <li>• Number of theoretical plates</li> </ul>	Redundant with lines 220-222.
XI.	696-698, 735-737, and 789-791	Clarification is needed regarding the statement: “... the minimum resolution between the active ingredient and the closest eluting impurity, or the two peaks eluting closest to each other, should be given.” Please add: “Other peak pairs may be used if the separation criteria provide assurance that adequate overall peak resolution will be obtained.”	Material to establish reference samples or standards may not be available for system suitability to prepare solutions used to measure resolution between the active ingredient and the closest eluting impurity or the two peaks eluting closest to each other. Other peak pairs can be used for resolution if the separation criteria provide assurance that adequate overall peak resolution will be obtained.

**Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)  
Detailed Comments (continued)**

Section	Lines	Comment	Rationale
XI. Methodology	701-702	Please delete the following sentence: The sequence of injection of blanks, system suitability standards, other standards, and samples should be defined.	This information is not needed in a specific analytical procedure and may be instead covered by a general standard operating procedure.
XI.	706-707	Please delete the following sentence: The effect of adjustments in mobile phase composition on retention times should be included in the analytical procedure.	Redundant with lines 337-341.
XI.	708-710	Please delete injection valves as an example of special HPLC equipment.	Injection valves are not unusual or unique pieces of HPLC equipment.
XI.	753-755	Please delete the following sentence: Validation criteria should include specificity (demonstrating no interference of placebo), linearity, repeatability, intermediate precision, and robustness.	Spectroscopic methods are usually used for identification, not quantitation. In addition, this information is redundant with the table given on lines 426-439.
XI.	773-774	Please change lines 773-774 as follow: Running buffer: composition	Though the composition must be specified, including the order of addition of the components is an inappropriate level of detail.
XI.	779	Please delete line 779.	Model of equipment is an inappropriate level of detail.
XI.	804-810	Please delete lines 804-810.	The discussion of enantiomeric excess is not necessary in this guidance.
XI.	835	Please delete line 835.	Solid samples are dissolved prior to performing size exclusion chromatography; therefore, it is not used to characterize particles.
XI.	871	Under Other Instrumentation, please add a section on Titrimetric Techniques.	Titrimetric techniques such as Karl Fischer are common analytical procedures used in the analysis of pharmaceutical substances and dosage forms. Guidance on this category of test would be useful.

**Draft FDA Guidance “Analytical Procedures and Methods Validation” (Docket No. 00D-1424)**  
**Detailed Comments (continued)**

Section	Lines	Comment	Rationale
Attachment A	901-902	Please change sections in lines 901-902 as follows: Stress Studies should refer to Section VII.A.2.b. Instrument output/raw data for impurities should refer to Section VII.A.2.c.	The draft refers to the incorrect sections. The letters “b” and “c” should be switched in lines 901 and 902.
References	960, 965, 967, 970-971, 975-976, 977-978, 979-980	Please reference the current revision of the following documents: <ul style="list-style-type: none"> <li>• ICH Q1A</li> <li>• ICH Q3A</li> <li>• ICH Q3C</li> <li>• ICH Q6A</li> <li>• USP</li> </ul>	

# LETTER

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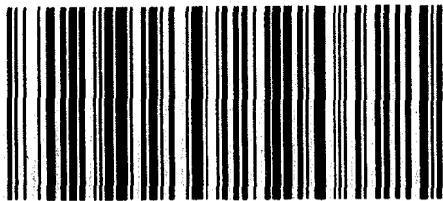
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