

*Johnson & Johnson*  
**CORPORATE ANALYTICAL SUBCOMMITTEE**

December 29, 2000

2786 '01 JAN -8 15:42

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

Re: Graft Guidance for Industry on Analytical Procedures and  
Methods Validation: Chemistry, Manufacturing, and Controls  
Documentation; Notice of Availability Appearing in the  
Federal Registration for August 30, 2000

Dear Sir/Madam:

The Johnson & Johnson Corporate Analytical Subcommittee (CAS), sponsored by Johnson & Johnson Worldwide Council of Research Directors (CORD), consists of analytical scientists from pharmaceutical, consumer, and professional sectors worldwide. The Subcommittee provides the Johnson & Johnson Family of Companies greater access to internal and external research and new technology resources. It coordinates programs and addresses scientific and technological issues of broad corporate impact.

The Subcommittee reviewed the draft guidance and agreed that the guidance provides a clear direction for development and validation of analytical procedures. We believe that the guidance serves to clarify many of the issues surrounding the development and validation of analytical procedures.

Enclosed are general comments compiled from several of the Johnson & Johnson operating companies engaged in the manufacture of pharmaceutical and consumer products.

The Subcommittee appreciates the FDA's consideration of these comments.

Sincerely,

Johnson & Johnson Corporate Analytical Subcommittee  
1125 Trenton-Harbourton Road  
Titusville, New Jersey 08560  
Attn: Joseph A. Albanese, Ph.D.

00D-1424

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*Joseph A. Albanese*

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Enclosed: General Comments

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**General Comments:**

**Lines 137 & 154:** A more specific definition of "other official sources of reference standards" would be helpful.

**Line 243:** Consider the addition of a statement that "*some of the items may be covered in an SOP, as appropriate.*"

**Line 248:** Except for unusual analytical methods, it seems that a statement of the principle of commonly used procedures, such as reversed-phase HPLC is unnecessary.

**Lines 251 - 254:** See comment for **Line 243**, above. The sampling procedures and number of replicate analyses per sample can be described in a SOP rather than in the method.

**Lines 291 – 292, 296 - 297:** A statement indicating the stability characteristics of the solutions (time, temperature requirements, as appropriate) should be included.

**Lines 302:** The sampling sequences can be described in a SOP rather than in the method.

**Lines 317 – 319:** Data reporting formats are often established within the LIMS system. Such laboratory practices should typically be defined in an appropriate SOP, not in individual analytical methods. Consider the addition of "*in an analytical procedure or a SOP*" to the end of the sentence.

**Lines 400-420, 455-520:** Information discussed should not be required as part of Method Validation data. Rather, they can be included and submitted as part of the analytical procedures and controls.

**Line 436 - 437:** The requirement for submission of representative instrument output in the event an effect is observed during robustness testing seems unnecessary as long as other relevant data such as resolution and/or elution order are reported.

**Line 450-453:** As part of the method validation experiments, information concerning the forced degradation (stress) studies is more appropriately included in the method validation report rather than in the stability section of the application.

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**Lines 498, 503, and 506:** A clear definition of "raw data" as it pertains to this guidance and submission requirements would be helpful.

**Lines 498 – 520:** It appears that there is considerable crossover of the information requested between the method validation and stability sections. It should be sufficient to include the information in either section, as appropriate without duplication in both.

**Lines 584 and 585:** For clarification of the use (or non-use) of compendial methods, it is suggested that the sentence be modified to read "...USP/NF analytical procedures, *if used*, are suitable for..."

**Line 625:** More specific references to appropriate statistical analyses would be helpful.

**Line 702:** The MSDS for common analytical reagents (such as common organic solvents for HPLC) should not be required.

**Line 817 & 879:** More specific information surrounding the demonstration of column equivalency would be helpful.

**Lines 819 - 832:** Certain column parameters, such as the hardware material, frit size, and filter type, should not be required unless they are unusual or critical for the analysis. Similarly, certain information on column packing material, such as particle type, pore diameter, surface coverage, percent carbon, additional silylation, and recommended pH range, should not be required. This information is implicit once the column manufacturer, packing material type, and particle size are identified.

**Lines 857 & 905:** It is suggested that the phrase "closest eluting impurity" be amended to read "closest *critical* eluting impurity".

**Line 862:** See comment for **Line 302**, above. The sampling sequences can be described in a SOP rather than in the method.

**Line 1044:** A discussion of the rationale for selecting the dissolution medium should not be required in the test procedure. It can be addressed in the applicant's internal research.

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