



July 23, 1998

Dockets and Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Rm 1-23
Rockville, MD 20857

4 4 7 7 '98 JUL 28 A11 :58

RE: Comments on Proposed Rule 21 CFR Part 99

To Whom It May Concern:

ALLERGAN appreciates the opportunity to comment on the proposed regulation concerning "Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics and Devices". The following areas are of particular concern.

99.101 Information that may be disseminated

Sec. 552 of the statute states acceptable literature includes:

(A) *Reprint or copy of an article...published in a scientific or medical journal...which is about a clinical investigation...*

(B) *Reference publication*

Comment:

The interpretation of this requirement is too literal as it disqualifies review articles, consensus statements, and other forms of communication found in scientific journals. Review articles, for example, could include comprehensive information about several clinical investigations without providing the level of detail of each individual study that is described in the proposed regulation. Likewise, consensus statements from Federal health agencies or Medical Specialty Societies are unacceptable by this definition, even though they potentially validate the new use of a drug as "standard medical treatment or therapy". This represents an unfair restriction for off-label uses of drugs, that in fact, may have a large base of clinical experience and are considered standard medical practice.

99.201(d)

The 60-day period shall begin when FDA receives a complete submission, including, where applicable, a certification statement or application for exemption. For purposes of this part, a submission shall be considered to be complete if FDA determines that it is sufficiently complete to permit a substantive review.

Comment:

The statute provides for a 60 day notification period in advance of disseminating information. Section 99.201(d) suggests there is a preliminary review process prior to the 60 day clock starting. Has FDA determined how it will be able to determine if a submission package is

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sufficiently complete to permit substantive review? The concern is that the 60-day time clock will not start until some undefined period of time. In addition, the wording in 99.201(d) appears to be inconsistent with the wording in 99.301.

Thank you for considering our comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Garbe', written in a cursive style.

Dave Garbe, Director
Scientific Information and Medical Compliance
Allergan

ALLERGAN

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TC-16



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BOTOX
Botulinum Toxin Type A
Purified Neurotoxin Complex

