



2740 '98 JUL 23 PI :14

July 23, 1998

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

RE: **Docket No. 98N-0222**
Comments on Proposed Rule, Dissemination of Information on Unapproved/New Uses for
Marketed Drugs, **Biologics**, and Devices

Dear Sir or Madam:

We are providing our comments on Docket No. 98N-0222, Proposed Rule, Dissemination of
Information on Unapproved/New Uses for Marketed Drugs, **Biologics**, and Devices,

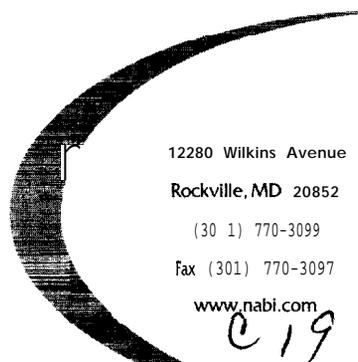
Each comment names the section of the proposed rule we are commenting on (**bold type**), the text
of the section (*italic type*), and our comment (**regular type**),

You may contact Jeff Smith, Senior Associate, Regulatory Affairs, at 301-255-6898, in regard to
these comments.

Sincerely,

Lewis Pollack, Ph.D.
Director, Regulatory Affairs

98N-0222



12280 Wilkins Avenue
Rockville, MD 20852
(301) 770-3099
Fax (301) 770-3097
www.nabi.com

019

Nabi®

Docket No. 98 N-0222

Comments on Proposed Rule, Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

99.101.b.1

The determination of whether a clinical investigation is considered to be “scientifically sound” will rest on whether the design, conduct, data, and analysis of the investigation described or discussed in a reprint or copy of an article or in a reference publication reasonably support the conclusions reached by the authors. Accordingly, a clinical investigation described or discussed in a reprint or copy of an article or in a reference publication must include a description of the study design and summary of results and conclusion pertaining to the new use. A clinical investigation presented in a format that does not represent a reasonably comprehensive presentation of the study design, conduct, data, analyses, and conclusions.. does not qualify for dissemination under this part.

An article may not meet the requirements as stated above due to the journal publisher’s space and format restrictions. If the company can provide supporting information that permits adequate FDA review of the study design, conduct, analyses and conclusion, the article should be allowed for dissemination,

99.103 .a.1.iv

If applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated.

Should the statement address adjuvant or supporting therapies?

99.201.a.3

An explanation of the manufacturer’s search strategy in selecting the articles for the bibliography (e.g., the databases and criteria used to generate the bibliography and the time period covered by the bibliography).

This is not required under Public Law 105-115, Section 401 and is an unnecessary requirement and burden, therefore this item should be eliminated. Furthermore, paragraph 99.20 1.a. 3 implies that a bibliography should be submitted every time, but according to 99.103 .a.3, a bibliography will be submitted only when one is not present in the information to be disseminated.

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 the FDA determines that it is sufficiently complete to permit a substantive review.

The FDA should inform the manufacturer within 30 days if the submission is incomplete. This allows the company to complete its package sooner and prevents wasted effort and delay in getting valuable information to the medical community.

Nabi[®]

Docket No. 98N-0222

**Comments on Proposed Rule, Dissemination of Information on Unapproved/New
Uses for Marketed Drugs, Biologics, and Devices**

99.301.a.4 and 99.501 .a.1.i

FDA may require the manufacturer to maintain records that will identify individual recipients of the information that is to be disseminated.

Although this option is provided for in the law, we feel this requirement would be an undue burden. The requirement for tracking recipients by category (99,501 .a. 1 ii) is more reasonable.