

The Oncologist

The International Peer-Reviewed Journal
for the Practicing Oncologist/Hematologist

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July 23, 1998

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12420 Parklawn Drive (Room 1-23)
Rockville, MD 20857

One page fax: 301/443-5 169
Re: 21 CFR Parts 16 and 99 [Docket No. 98N-0222]
Dissemination of Information . . .

Dear Peggy:

Many thanks for ensuring that this commentary reaches the correct hands.

Commentary:

In support of the FDA's implementation of the *Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices*, we respectfully suggest that the FDA inform the appropriate journal editors of the detailed review criteria which the FDA will use in the evaluation of published material. By knowing in detail of these criteria, journal editors may proactively call the reviewers' special attention to those areas of FDA concern. In this way, off-labeled uses of drugs, biologics, and devices which are submitted for publication consideration would receive peer-review, which takes into account the particular areas the FDA considers of special import. The end result would be to further strengthen the peer-review process and, hopefully, speed and streamline the FDA's subsequent review of published papers which might be considered under the "off-label dissemination" provision. Although the autonomy of each journal would remain inviolate, the FDA's review criteria would, we are sure, be seriously considered by the respective journal editorial boards. We can certainly pledge this on behalf of *The Oncologist*.

If we may provide any further information, please contact

Yours sincerely,

Dr. Martin J. Murphy, Jr.
Executive Editor

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