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Dickinson's FDA REVIEW
Dickinson's FDA UPDATE

1996 '00 JAN -5 P158

December 29, 1999

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

To Whom It May Concern:

Re: Docket No. 99N-4784 — Premarket Notification: Requirement for Redacted Version of Substantially-Equivalent Premarket Notification

This comment, which is from a long-experienced publisher and commentator on FDA activities, objects to several aspects of the proposed rule because they abdicate FDA responsibility to assure that redaction of content from publicly-released 510(k) documents is objective and in the public interest. As proposed, the rule would permit manufacturers of 510(k) devices to subjectively determine without effective FDA interference what material in their 510(k) submission will be withheld from public disclosure. Under the rule as proposed, material redacted by the 510(k) sponsor may not meet the statutory criteria of "trade secret, commercial or confidential" and may be unduly broad to suit the convenience or other non-statutory objectives of the sponsor.

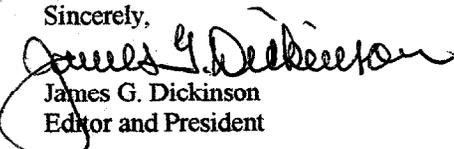
Although the preamble to the proposed rule states that FDA is not delegating to 510(k) sponsors its exclusive authority to determine the appropriateness of sponsor redactions, it also states that the agency will "not routinely review each redacted 510(k)" and that except in cases of "clearly abusive redactions ... FDA will rely on parties that request a 510(k) ... to raise any issue of excessive redaction." This is an unrealistic burden to place on requesters, especially requesters who are not sophisticated members of industry, such as direct competitors of the sponsor who has excessively redacted its own 510(k).

Because the proposed rule is driven by FDA's need to conserve resources by shifting its burden of 510(k) redaction to the sponsor, workaday reality in practice will mean that there will be little or much-belated public objection to excessive redactions by sponsors, except when direct competitors take exception. The net effect of the proposed rule in this respect will therefore be to remove from public access, albeit unintentionally, information to which the public is entitled under the Freedom of Information Act. This statute was not enacted with the convenience of either FDA or the industry in mind; the proposed rule tends to emasculate the spirit of the FOIA.

In the preamble to the proposed rule, FDA even goes so far as to encourage industry sponsors to submit their 510(k) redaction in portable document file (.pdf) format. While this format is efficient and convenient, it is not normally amenable to editing and would further diminish the chance that FDA could, as a practical matter, overrule part of a submitted redaction (not that FDA intends to even look at redactions unless it gets a complaint).

To mitigate the objections presented above, FDA should change the proposed rule to provide that sponsors must submit written justifications for each redaction so that these may be at least randomly reviewed by FDA. Also, FDA should state in the rule that electronic formats such as .pdf that cannot be edited will not be accepted for FOI documents, thus preserving FDA's capacity to audit and alter redactions submitted by 510(k) sponsors.

Sincerely,


James G. Dickinson
Editor and President

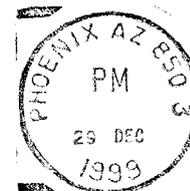
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