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Dockets Management Branch (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20857

Dear Dockets Manager:

We wish to comment on the proposed rule published Dec. 21, 1999 entitled, "Pre-market Notification: Requirement for Redacted Version of Substantially-Equivalent Pre-market Notification." We also wish to request that this proposed rule be withdrawn. Four Reasons for this request are listed and discussed in detail below.

A. The proposed method of complying with the FOI Act will lay a heavy and unnecessary burden on the very large majority of small manufacturers that comprise the medical device industry and who have built this industry into the global leader it is today.

1. Despite the large staff currently dedicated to FOIA responses in the Center for Devices and Radiological Health (CDRH) and FDA in general, the "significant backlog" mentioned in the 2nd paragraph on p. 71348 has increased so that it often takes from 1 to 3 years to obtain a copy of a 510(k) that has not been redacted from a previous request. It appears this staff of trained and dedicated personnel cannot keep up with the occasional request (we estimate that perhaps 30 % of all 510(k)s have been redacted in the past) for a 510(k) to be redacted. Thus, the load on industry when all 510(k)s must be redacted will be enormous.

2. Many small- to intermediate-sized firms do not feel qualified to prepare their own 510(k)s so they contract with one of the many firms that specialize in this area. If this proposal becomes a final rule, these same firms will also have to pay the price of having their 510(k)s redacted. This demand will result in the development of yet another group of specialists in the art and science of redaction, with no significant gain to the industry!

B. The proposed method is unworkable for several reasons.

1. The proposal makes much of the firm being "in the best position to identify trade secret and confidential commercial information." This may be true but our years of experience with industry, inside and outside of FDA, show that many firms do not have the training to recognize what is trade secret and commercial information--as interpreted by FDA--and would claim that everything in the 510(k) fell under this cover. Further, industrial personnel usually are not specialists at redacting material which is an art in itself. We quote from the top

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paragraph, column 3, page 71348, "It has been FDA's experience that many 510(k) holders who are provided predisclosure notification by the agency fail to respond adequately; they may not provide an appropriately redacted 510(k), ..." This becomes of importance since as stated in the 3rd paragraph, 3rd column of page 71350, "**FDA retains exclusive authority to make final determinations** concerning whether or not a redaction is permitted under FOIA and is **not delegating this authority** to any person required to submit a redacted 510(k)."

In this proposal, the FDA is violating a basic principle of management by proposing to delegate the **responsibility** without delegating the **authority** to do the required work.

2. A perhaps more important point arises under this subject. The second paragraph of page 71350 states that, "FDA intends to make all redacted 510(k)s available through the internet regardless of whether a FOIA request has been received." The internet seems infinite at this time but we suggest it is not really necessary to clutter FDA records on the internet with from 4000 to 5000 redacted 510(k)s each year when only a small fraction would normally be requested. Many 510(k)s, particularly for Class III preamendment devices, depend on the use of copyrighted articles summarizing clinical studies to prove "substantial equivalence." Many of these 510(k)s contain ~~from~~ hundreds of pages. We would point out that only **summaries** of PMA's are available under FOIA.

3. This proposed process may have a result the FDA has not envisaged. Namely that firms of this highly competitive will, for the first time, have the materials to challenge **all substantial equivalence decisions** the FDA may make. Considering the litigious nature of business in the United States, this may lead to enough lawsuits to consume **even more** of FDA's scant resources to defend the reasons for a given decision.

C. The proposed method does not properly protect copyright, patent and intellectual property rights of publishing scientists or of the submitting firm.

1. It may be legal for the FDA to provide copies of copyrighted materials to an individual in response to a FOIA request. We do not believe it is legal (and certainly not reasonable) for the FDA to put such copyrighted material on the internet where it is readily available to millions of anonymous computer owners. Surely, this is not a "fair use under the copyright Act of 1976"!

2. Forcing a company to accede to putting their instruction manuals, which may be copyrighted, on the internet--if they wish to get clearance of their 510(k)--is highly questionable. The suggestion that the firm might wish to "rewrite" their instruction manual for internet publication also is questionable and represents totally wasted effort.

3. We see no reference to protection of patented materials and other intellectual properties. It should be remembered that "patentability" does not rule out "substantial equivalence." Although a "new" device entering the market may be substantially equivalent to other devices (in use and safety and effectiveness), it may be unique enough to have several patentable features. In addition, detailed machine drawings of a device may reveal considerable valuable information to the competition without being patentable. These could be redacted, if the FDA would permit, but we doubt if it would permit this in many cases.

D. The proposed method for meeting FOIA requirements is unnecessary; there are better alternative approaches to decreasing the FOIA load on FDA's scant resources--the probable reason for this proposal.

1. Because we have been critical of the proposed process, we will suggest what we believe would be highly workable alternatives. An obvious but undesirable alternative would be to continue current practices but to seek user fees to provide for increases in the reviewing/redacting staff where (or if) they overlap.

2. Another alternative, both workable and desirable, would be to make the 510(k) process more parallel to the PMA process. This could be accomplished by modifying Section 513(i)(3), to omit the possibility of a submitter providing a "statement" that he will provide the data on safety and effectiveness within 30 days. FDA, in this proposal admits that this "statement" is not effective in that, "many 510(k) holders who are provided predisclosure notification by the agency fail to respond adequately." The only other change required would be within the administrative purview of FDA, to enforce the requirement that the "summaries" provided under this section be truly "adequate", as the section now requires. Many reviewing divisions already do this. Those of us who prepare 510(k)s have had their 510(k) clearance held up until the "Summary of Safety and Effectiveness," was considerably revised to contain the required information. As is currently done, these "adequate" summaries could be placed on the internet.

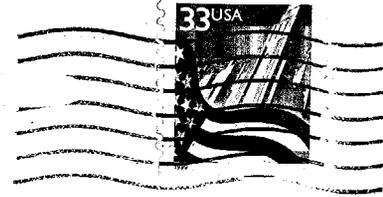
If the changes we propose were made to Section 513(i)(3) and the accompanying change in operating procedure were made, the 510(k) process would be more similar to the already proved PMA process. We believe this would allow FDA to attain its goal of decreasing government resources to respond to FOIA requests without doing violence to the intellectual property rights of medical device firms or forcing them into the undesirable and expensive FOIA business of redacting 510(k)s. Your consideration will be appreciated.

Sincerely,

  
Neal Dunning Assoc. Inc.

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