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

RE: Docket No. 99N-4784; Proposed Rule: Premarket Notification;  
Requirement for Redacted Version of Substantially-Equivalent Premarket  
Notification, 64 Fed. Reg. 71347, December 21, 1999

Dear Madam/Sir:

We are submitting these comments on behalf of the Contact Lens Institute, an association of research-based manufacturers of contact lenses and lens care products regulated by the FDA.<sup>1</sup> Many of the products developed and marketed by CLI members are Class II medical devices and are the subject of 510(k) notification requirements. Many of the 510(k) notifications submitted by CLI members are complex, multivolume submissions including extensive reports of clinical and preclinical studies relating to the subject products.

The proposed FDA regulation would require submitters of all new 510(k) notifications submitted after the effective date of the regulation to prepare and submit redacted versions of those notifications within 30 days of the substantial-equivalence determination. The adoption of such a requirement would exceed FDA's legal authority under the FOIA and the FFDCA and would be an unjustified regulatory burden on the entire medical device industry. The proposed regulations establishing procedures for the pre-request submission of redacted 510(k) notifications should be modified, if adopted, to provide that the submission of such redacted documents under those procedures be permitted, not required.

<sup>1</sup> The members of the Contact Lens Institute are Alcon Laboratories, Allergan, Bausch and Lomb, CibaVision, CooperVision, Vistakon, Wesley Jessen.

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### **FDA Lacks The Legal Authority To Impose A Requirement For Routine Pre-Request Preparation of Releaseable Versions Of 510(k) Notifications**

In the proposal, FDA does not argue and, indeed, it has never argued that the FOIA or any other statute requires the agency to place on public display every 510(k) notification which it receives for a substantially-equivalent device. To the contrary, FOIA requires only that the agency respond to requests for such documents. Moreover, the agency has long-established procedures for processing such requests, which are triggered only when a specific request for such documents is received. Thus, while certain categories of agency documents are required to be placed routinely on public display and, now, to be posted on the Internet, 510(k) notifications have never been subject to such universal posting requirements and the FDA has not asserted otherwise.

Congress has addressed the timely public availability of 510(k) information in a manner that is different and, indeed, flatly inconsistent with the current FDA proposal. For instance, in 1990, when Congress enacted the Safe Medical Devices Act, it did not require the pre-request submission of redacted versions of 510(k) notifications. Rather, it mandated that submitters of 510(k) notifications either a) provide FDA with a summary of the safety and effectiveness information contained in the notification, which would then be readily available to the public upon request to the FDA, or b) provide FDA with a commitment that the submitter itself will disclose 510(k) information directly to members of the public upon request. By this mandate, Congress clearly expressed the judgment that this supplementation of the FOIA process – as opposed to changes in the FOIA process itself -- was an appropriate means of assuring that information about new substantially-equivalent devices is available to the public on a timely basis. There is no indication that Congress was incorrect in this regard or that, if it were, FDA has been authorized to impose additional requirements in this area in the absence of further legislative authority. Moreover, if the FDA proposal were adopted, there would no longer be any incentive at all for 510(k) submitters to provide “summaries” of their safety and effectiveness data – even though the “summary” requirement was touted at the time as one of the significant new aspects of the

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1990 amendments.<sup>2</sup>

It is true, of course, that in those cases where 510(k) submitters have chosen to provide safety and effectiveness summaries instead of a commitment to release 510(k) documentation directly to the public upon request, FDA may still be presented with requests under the FOIA for copies of releasable portions of the actual 510(k) notification. The general principle under FOIA still applies, however, that, until such requests are received, neither FDA nor the submitter have any legal obligation to prepare a “releasable” version of the 510(k) – a document that would have no utility other than for responding to an FOIA request that may never be made. While it is also true that the procedures for redacting the exempt portions of a 510(k) notification, including appropriate consultation with the submitter where possible, can be more time-consuming than the statutory FOIA timetables, this has been true for decades without either Congress or the Courts authorizing FDA to adopt new regulatory burdens on the submitters of those notifications.

The limitations on FDA’s authority in this regard are underscored by the fact that Congress has declared that the costs of responding to FOIA requests be borne not by FDA, not by taxpayers, and not by regulated industry, but by requestors. On this basis, FDA is required to impose “user fees” on FOIA requestors which are adequate to cover the agency’s costs of handling their requests. Thus, to the extent that FDA’s proposal seeks to shift from FDA to industry the burden of responding to FOIA requests, the proposal would thwart the clear intent of Congress in this regard (modified only as it specifically provided in the 1990 amendments).

FDA’s current proposal also conflicts with the specific Congressional mandate in the Electronic Freedom of Information Act Amendments of 1996 which requires FDA to post on its web site electronic versions of agency documents that have been already been released under the FOIA and which the agency determines are likely, because of their subject matter, to be the request of additional requests. (5 U.S.C. §552(a)(2)(D)) FDA has interpreted this provision in its internal

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<sup>2</sup> For many interested persons, a 510(k) summary of safety and effectiveness data is likely to be far more useful, and far more cost effective to request, than the mass of documentation that is included in a complex 510(k) notification supported by extensive clinical trial data.

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Regulatory Procedures Manual on Information Disclosure to cover:

any document that is disclosed in response to a FOIA request and that FDA determines has become or is likely to become the subject of subsequent (i.e., three or more) requests for substantially the same record. . . .

This approach maintains the proper historical balance under the FOIA, in which most agency documents need only be made available (and redacted, if necessary) upon request, and upon the payment by requesters of the applicable user fees. This approach, however, is fundamentally inconsistent with the broad mandate FDA has now proposed which would require the preparation of redacted 510(k) notifications and the immediate posting of those documents on the agency's web site even before a single request for those documents has been received.

For these reasons, while the proposed procedures would facilitate the handling of redacted versions of 510(k) notifications in those instances where applicants choose to submit them, either before or after they are the subject of an initial FOIA request, there is no legal authority or justification for FDA to attempt to impose such requirements across the board on all 510(k) notifications regardless of whether they have been, or are likely to ever be, the subject of any FOIA request.

### **FDA Has Not Identified An Adequate Factual Justification For Imposing This Additional Regulatory Mandate On The Medical Device Industry**

Significantly, the Federal Register proposal not only fails to identify a legal basis for mandating routine pre-request preparation of "releasable" versions of substantially-equivalent 510(k) notifications, it also fails to provide adequate factual justification for making the procedures mandatory, as opposed to voluntary. Most glaringly, while providing statistics on the numbers of 510(k) notifications received and accepted in a year, the notice provides no information whatsoever on the number of FOIA requests that are received in a year for 510(k) notifications that have never previously been requested and released. In the absence of this information, there is no way of assessing the additional burden of requiring redacted versions to be prepared of all of those notifications despite the fact that information about many of them will never be requested or, if requested,

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will be satisfied by release of industry-prepared summaries of safety and effectiveness information.

Moreover, the agency makes no distinction between the burden of redacting a large complex 510(k) notification supported by extensive clinical and preclinical data and the burden of identifying and redacting the confidential information in a typical 510(k) notification. Thus, the agency simply assigns an "average" 2 hour time period to this task. The experience of CLI members is that identifying the confidential portions and producing a specially redacted version of a complex 510(k) for a contact lens or contact lens care product can take several times as long as the agency estimates, including both professional and clerical time, plus the costs of copying and shipping and/or conversion and transmission in electronic form. For the reasons identified by the agency in its proposal, CLI members usually undertake this effort voluntarily in response to notification from FDA that an FOIA request has been filed for one of their submissions. There is no reason, however, why this burden should be shifted by regulation to a submitter who does not wish to undertake this effort in anticipation of the possibility of an FOIA request that has not yet been made.

**Conclusion**

For the foregoing reasons, CLI supports the proposed regulation only in so far as it provides additional procedures for handling redacted 510(k) notifications and for making them available to the public in an efficient manner. CLI opposes, however, as both legally and factually unjustified, the proposal to mandate the blanket application of these procedures to every 510(k) notification that receives a substantial equivalence determination.

Respectfully submitted,



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