



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5500 Fishers Lane, GCF-1
Rockville, MD 20857

February 1, 1996

NOTE TO BRUCE BURLINGTON, M.D., AND JOE LEVITT

Re: List of Items for Which OCC Review Is Not Necessary

As you know, the Office of the Chief Counsel has recently undertaken a redesign initiative intended to make our office more effective in providing legal services that help our clients achieve their important public health goals. We have very much appreciated Joe Levitt's active and extremely valuable participation in that effort.

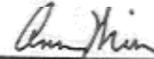
As one important element in the effort to set priorities and best use OCC resources, we have also considered whether there are categories of documents currently reviewed by our office for which we can decide that OCC review is not necessary. We have tried to identify such categories so that we will be able to focus OCC efforts on those matters that present the more difficult or controversial legal issues and resolve those more promptly. After discussions with Joe Levitt, we have decided to forgo OCC review of items in 10 of the categories identified in the attached list immediately. After developing formats (drafts to be sent to OCC by Joe Levitt by March 1, 1996, and final versions to be agreed upon by OCC and CDRH by April 15, 1996) and conducting training sessions, we will forgo OCC review of items in an additional 5 categories on the list by June 1, 1996.

In order to evaluate this approach, we have agreed upon a process for making the determinations about particular documents, for recording those decisions, and for mutually evaluating the process at the end of six months (i.e., at the beginning of August 1996). We have agreed to the process and to the approach to evaluation in the attached document.

Your Center has led creatively in its efforts to manage its workloads more effectively and predictably, and we very much appreciate your leadership. Your approach to identifying top

priority regulations and setting up teams to develop those regulations in a timely way has been an especially valuable model.

We also very much appreciate your support of our cooperative efforts to enhance the value of our legal services to CDRH and to the entire agency. We will continue to look for ways to work together even more efficiently and effectively.



Ann Wion
Ann Wion
Deputy Chief Counsel
for Program Review

Attachments

cc: Margaret Jane Porter (GCF-1)
Michael Friedman, M.D. (HF-28)
William Schultz (HF-22)
Edwin Dutra (HF-26)
Alicia Abbott (HF-26)
Joseph Sheehan (HFZ-084)
Eric Blumberg (GCF-1)
Kay Cook (GCF-1)
David Dorsey (GCF-1)
Linda Kahan (GCF-1)
Beverly Rothstein (GCF-1)
Barbara Stradling (GCF-1)

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LIST OF CDRH ITEMS FOR WHICH OCC REVIEW IS NOT NECESSARY

As of February 1, 1996:

1. Summaries of safety and effectiveness for PMA's
(previously agreed to)
2. Proposed and final rules under section 515(b)(2) of the act
to require that devices have an approval of an application
for premarket approval
(previously agreed to)
3. Notices under section 515(b)(3) terminating a proceeding to
issue a rule to require that a device have an approval of an
application for premarket approval
(previously agreed to)
4. Notices of availability of CDRH guidance documents
--Not included are notices for documents relating to
enforcement activities or that establish new or significant
policy
--OCC will review underlying guidance documents as in the
past, until agency-wide process for review of guidance
documents is developed
5. Notices of public meetings and conferences held by CDRH,
except public hearings before the Commissioner under 21 CFR
Part 15
--OCC will review notices of public meetings and conferences
if there is an unsettled or significant legal issue.
6. Notices extending the comment period for proposed rules
7. Jurisdictional requests from the Consumer Product Safety
Commission unless CDRH requests OCC input because of change
in prior position or unsettled legal issues
--CPSC should send requests directly to CDRH; CDRH should
respond directly to CPSC unless requesting OCC review as
described above

8. Citizen petitions, as follows:

a. Moot petitions

The agency has either effectively granted the petition because of past agency action or, due to external events, cannot grant the petition.

b. Repetitive issues

The agency has issued responses to other petitions on the same issues or addressed the same issues in other documents already reviewed by the Office of the Chief Counsel.

c. Purely scientific issues (not legal issues)

Review of such petitions is considered analogous to review of applications in that it requires exercise of CDRH's medical and scientific judgment.

d. Administrative discretion

Requests to institute a program not required by law or to develop a guideline or other type of guidance document.

e. Settled legal issues

A legal issue is raised, but it is a settled issue and OCC has reviewed and approved the response to the legal issue previously.

If a legal challenge is likely, then OCC should review the response, even if it might fall within one of these categories. If a non-settled legal issue is raised in the petition response, OCC should review the response.

9. Housekeeping regulations where no proposal is required

--For example, name and address change in regulations

10. CDRH correspondence that does not raise unsettled legal issues

As of June 1, 1996:

11. Notices of panel recommendations and proposed and final regulations to classify devices under 513(d), or to change the classification of a device under 513(e), and to revoke, because of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device
12. Notices of panel recommendations and final rules in response to reclassification petitions under section 513(f)
13. Proposed and final rules responding to reclassification petitions filed under section 514(b) or 515(b) of the act
14. Final rules codifying reclassification orders issued under section 520(1)(2), and proposed and final rules requiring a device to remain in class III or revising its classification under section 520(1)(5)
15. Proposed and final rules requiring a device to remain in class III or revising its classification under section 515(i)

February 1, 1996

PROCESS FOR DETERMINING WHICH PARTICULAR CDRH ITEMS WILL
NOT BE SENT FOR OCC REVIEW AND FOR EVALUATING APPROACH

Each determination that a particular document falls within a category not to be reviewed by OCC will be made by Joe Levitt or his designee and recorded as part of the endorsement record (except for correspondence).

In order to be able to evaluate the approach, CDRH will keep in a separate file copies of these documents that have not been reviewed by OCC. At the end of six months, CDRH and OCC representatives will evaluate the success of the program. An OCC representative will look at the items in the file that were not reviewed by OCC to determine whether OCC agrees with the categorization.

In addition, OCC and CDRH representatives will consider what effects or the determinations, if any, can be identified--e.g., any litigation or incorrect legal positions related to documents not reviewed by OCC, additional resources spent by CDRH because of absence of OCC review, saved OCC resources, and timeliness of issuance of these and other documents that OCC continues to review. In other words, after six months OCC and CDRH will mutually assess the costs and benefits of this approach and make any appropriate adjustments.