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Report to the Commissioner, Food and Drug Administration, Department of Health and Human Services

April 1987

DOCUMENT REQUESTS

Response Time to Congressional Committees Could Be Improved

GAO/HRD-87-45

GAO

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General Accounting Office
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Human Resources Division
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April 24, 1987

Frank E. Young, M.D., Ph.D.
Commissioner, Food and Drug Administration
Department of Health and Human Services

Dear Dr. Young:

At the request of the Chairman, Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Operations, we reviewed the Food and Drug Administration's (FDA) procedures for responding to requests for documents from chairmen of congressional committees. The Chairman expressed concern that FDA's continuing delays in providing documents to the Subcommittee has adversely affected its ability to oversee FDA's regulatory activities.

We reviewed FDA's handling of requests, made by committees from January through March 1986, for documents. In performing our work, we reviewed FDA records and interviewed officials in FDA's Office of Legislative Affairs, which is FDA's focal point for responding to congressional inquiries, and FDA's Centers, where the requested documents were located. The scope and methodology of our work, as well as the conclusions, are discussed in detail in appendix I.

We found that, although FDA provided requested documents to committees, it seldom provided them by the dates requested. The FDA Centers and offices involved in processing the requests delayed completing their work for one or more of the following reasons:

- They lacked written guidance concerning their roles and responsibilities.
- They lacked sufficient resources to process responses to requests promptly because of other competing demands.
- They were not required by FDA to meet internal target dates for completing their work.

Although some delays were warranted, we believe that FDA can take several actions to improve its responsiveness to committees' requests for documents. We recommend that you

- provide written guidance to FDA's offices on their responsibilities for responding to document requests;
- require that internal target dates be established for responding to requests and requesters be advised when dates cannot be met; and

- direct your Office of Legislative Affairs not to delay releasing documents while it prepares document lists or resolves questions about whether additional documents, which may contain trade secrets, can be released (see p. 14).

Your comments on a draft of the report have been incorporated, where appropriate, in appendix I; your comments on our recommendations are included in appendix II.

We are sending copies of this report to the Chairman, Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Operations; the Secretary of Health and Human Services; and other interested parties.

Sincerely yours,

David P. Baine

David P. Baine
Associate Director

Contents

Abbreviations

FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic
HHS	Department of Health and Human Services
OLA	Office of Legislative Affairs

Response Time to Congressional Committee Document Requests Can Be Improved

The Food and Drug Administration (FDA) administers various laws including the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938, as amended (21 U.S.C. 301), to protect the public health of the nation against hazardous foods, drugs, and other products. FDA responds to numerous inquiries and requests for information from congressional committees concerning its oversight of these products.

Requested documents may include memoranda of meetings and inspection reports involving regulated industries, correspondence, proposed and final regulations, minutes of meetings, records of telephone calls, and information on various regulatory programs and activities. According to officials from FDA's Office of Legislative Affairs (OLA), these documents usually contain confidential or sensitive information and may contain trade secret[1] information. Confidential information includes commercial data not available to the general public. Sensitive information includes pending decision memoranda addressed to the Secretary of the Department of Health and Human Services (HHS) and investigative files. Trade secret information is referred to in section 301(j) of the FD&C Act, which precludes FDA from revealing trade secret information to persons outside HHS.

OLA has overall responsibility for processing requests for documents, and it forwards the requests to one or more of FDA's Centers[2] or other offices where the documents are located. The Centers or other offices retrieve the documents from their files, review them for trade secrets, and forward them to OLA. OLA reviews the documents for sensitivity before they are released. Two sets of the documents are copied. The FDA office in which the documents are located may make the copies or OLA or both may make the copies; then one set is provided to the requester, and one set is retained by OLA. OLA prepares a listing of all documents provided; OLA also prepares a letter, to the committee chairman, and sends it with the documents and the listing. A copy of the letter and the listing is also sent to the ranking minority member of the committee.

Scope and Methodology

Our work was performed between January and December 1986 at FDA headquarters in Rockville, Maryland, where committee requests are

[1]Trade secret information can include unique methods, formulas, and manufacturing processes of FDA-regulated firms

[2]FDA has four centers. Center for Drugs and Biologics, Center for Food Safety and Applied Nutrition, Center for Devices and Radiological Health, and Center for Veterinary Medicine

received and processed. We identified committees' requests for documents received by FDA from January through March 1986, a period for which FDA had information indicating the dates requests were received and responses provided. OLA officials believe the January through March 1986 period covered by our review, during which 17 requests were received, was typical of FDA's workload. We computed the length of time it took FDA to respond to 12 of these requests[3] ; for each, the requester had specified the dates the documents were needed.

FDA does not routinely maintain records of the time each Center or office takes in responding to requests for documents. From the staff at OLA and the Centers, we obtained information on the general reasons for lateness in responding to committee document requests; for six of the requests, we obtained information on the specific reasons for lateness. We focused on these six requests because they were still being processed during our review. We also discussed with the staff the appropriateness of their procedures and practices to assure prompt responses to requests for documents.

Our work was performed in accordance with generally accepted government auditing standards.

FDA Seldom Met Due Dates

The 12 requests we reviewed involved documents related to such regulatory issues as antibiotics in animal feed, food labeling, product tampering, and drug approvals. Each request involved from one to several hundred documents. According to the OLA deputy associate commissioner, FDA provided committees over 15,000 pages of documents during this period.

Congressional requesters generally asked FDA to provide requested documents within 1 week of the date FDA received the request, but FDA responded to only 1 of the 12 requests within this time, taking an average of 41 days; responses were late by an average of 34 days, including a range from 1 day to over 4 months.

FDA provided partial responses for 3 of the 12 requests, but none of the 3 partial responses were provided by the specified date.

[3]Three requests did not specify due dates; one request had a due date that was deferred by the requester and FDA to an unspecified future date, and FDA lacked sufficient records for us to determine processing time for another request

Reasons for Delayed Responses

Lack of written guidance on the roles and responsibilities of FDA Centers and other offices contributed to the delays in processing document requests, as can be seen in the following: (1) Tasks associated with responding to requests were sometimes delayed or shifted from the Centers or other offices to OLA because of lack of available staff. (2) FDA's practice of copying two sets of documents and listing documents provided to committees was time consuming. (3) OLA spent time reviewing documents for trade secrets that had already been reviewed by the Centers. (4) Internal target dates were not required; target dates that were established were not required to be met.

Unclear Responsibilities Allow Work to Shift to OLA

FDA's staff manual guide designates OLA as the "focal point" for responding to congressional inquiries, but does not state the specific responsibilities of OLA, the Centers, and other offices. OLA interprets its responsibilities for congressional inquiries (such as committee requests) as including any duties necessary to provide a response as promptly as possible, taking into account other competing workloads. The Centers interpret their responsibilities as providing requested documents to OLA and performing trade secret reviews when necessary. According to OLA officials, OLA gives oral guidance to the staff of the Centers and other offices.

The lack of clearly defined responsibilities for handling committee document requests has allowed the Centers and other offices to shift tasks, such as copying documents and reviewing documents (for trade secrets), to OLA when work priorities compete for available staff time. However, OLA did not always have staff readily available to carry out these tasks promptly.

Time-Consuming Tasks

Because the documents requested are sometimes voluminous, OLA officials told us that copying and listing documents to be provided to committees are sometimes the most time-consuming tasks associated with responding to requests.

Two sets of the documents are copied—one for the requester and one for OLA's files. Sometimes the Centers or other offices copy one set of the requested documents and forward them to OLA staff, who said they later make the second set. However, OLA staff make both sets if the Centers or offices with the original documents do not have staff available to copy them because of other competing demands. In such cases, the Centers or offices forward their original files to OLA.

OLA officials said it is necessary to retain a set of documents because they may have to refer to them later if committee staff have questions about information in the documents. In addition, some of the original documents come from FDA's field offices or 1 of the 13 offices in the Washington metropolitan area; these documents would not be readily available if there was a need to refer to them. In addition, OLA officials said that FDA officials may ask to look at documents provided to committees if hearings are subsequently held on the issues addressed in the documents.

OLA officials said that, before providing documents to the committees, they prepare itemized listings of the documents in the event OLA's file copies are lost, misfiled, or sent to storage. They stated the most important reason, however, is to save time in locating specific documents within a voluminous set when committees call with questions about documents they have received. According to OLA officials, their support staff are not always available to promptly copy or list documents because of other competing work. The officials said that this was the reason for the delay of three of the six requests being worked on at the time we initiated our work.

During a March 1986 meeting with an OLA assistant director for congressional operations, we observed stacks of documents on the floor because staff were not available to make copies; these documents were for responding to one of the three requests. The committee had requested that the documents be provided by February 14, 1986; the assistant director told us that some of the documents (which were in response to a request for a voluminous set of documents) had been given to the committee on February 21 and March 20. He said that because support staff were not available, he, himself, copied many of the documents. FDA provided the remainder of the documents to the committee on May 16, 1986, 91 days after the requested due date. The other two requests for which OLA staff were not readily available for copying were 17 and 129 days late. OLA staff could not estimate how much time was attributable to copying and listing these documents, but said these tasks could have taken several days.

OLA staff said they use the listings of documents to provide general assurance that the requested information is complete before the documents are transmitted to the committees. FDA also provides copies of the listings to ranking minority members of the committees to inform them of the documents being requested by the committee chairman. To determine the need for this information, we spoke with the minority staffs

from three committees that frequently request documents from FDA These staffs said they appreciated being informed of the subject matter of documents being provided to the committee and found the listings useful.

Trade Secret and Sensitivity Reviews

Before documents can be released to committees, FDA must review them for trade secrets. Documents are also reviewed for sensitive or confidential information. FDA has not developed written guidelines, however, for identifying trade secret or sensitive information.

FDA's regulation (21 C.F.R. 20) concerning the release of information to the public is used as guidance in making trade secret determinations. The regulation provides a general definition of "trade secret" information and makes reference to specific categories of FDA records for the various products FDA regulates. According to OLA officials, OLA must assure that all requested documents are reviewed for trade secrets by the Centers. OLA also reviews the reasonableness of the Centers' determinations. According to an OLA official, these reviews relate to trade secret deletions made by the Centers and not to whether the documents may still contain trade secrets not identified by the Centers.

According to OLA officials, in cases where the Centers do not review the documents for trade secrets before they are referred to OLA, OLA staff are supposed to review the documents to determine whether they contain formulas or methods of processing that might be considered trade secrets. However, officials said their staff only make determinations that documents do not contain formulas or processing methods because the staff do not have the expertise to determine what is a trade secret. OLA officials also said that if the documents contain formulas or processing methods, the trade secret determinations must be verified or made by the Centers or the general counsel (because they are considered the experts in these matters). OLA staff said OLA performed the only review for trade secrets for three of the six cases we focused on.

OLA's deputy associate commissioner told us that the definition of "trade secret" is complex and thus determinations concerning trade secrets can be subjective. He said the Centers sometimes designate more information than necessary as being "trade secret." When this occurs, release of documents is delayed until the questions are resolved.

According to OLA officials, they sometimes must forward sensitive information, such as draft regulations or liaison documents, to other appropriate FDA and HHS offices for additional review. The purpose of additional reviews of sensitive documents, according to the OLA deputy associate commissioner, is to (1) inform appropriate agency officials of committee requests and (2) decide if it is necessary to explain to committees the sensitive nature of the information and ask that they not release the information to the general public.

The number of reviews performed on each document and the time taken to perform them varied. According to OLA staff, three of the six requests we reviewed, because of sensitive information, underwent additional reviews at other FDA and HHS offices. The first request for information, pertaining to an ongoing FDA investigation, underwent three additional sensitivity reviews, according to an OLA assistant director for congressional operations: one by HHS's general counsel, which took about 1 week; one by HHS's Office of the Assistant Secretary for Legislation, which took about 3 weeks; and another by FDA's Office of Regulatory Affairs, which took more than 1 month. The Office of Regulatory Affairs took more than 1 month because its staff was involved with a food-tampering crisis at the same time it was requested to perform a sensitivity review. FDA's overall response to the request (which required three sensitivity reviews) took 131 days to complete. FDA, however, provided two partial responses to this request, 33 and 67 days after the due date.

Another OLA assistant director for congressional operations said that the second request, for a draft (not final) memorandum, involved sensitive information; the response was delayed to allow FDA time to complete its reviews and reach agreement on how to explain this sensitivity to the committee. Additional reviews were performed by FDA's Division of Veterinary Medicine, the associate commissioner for management and operations, HHS's general counsel and HHS's Office of the Executive Secretary. The OLA assistant director could not recall how long each office took to complete its review, but FDA responded to this request 28 days after the date specified by the committee. A third assistant director for congressional operations said that the third request underwent one additional review—by HHS's general counsel, which took only 1 day to complete.

Internal Target Dates Not Required for Completing Work

FDA does not have a written requirement that (1) internal target dates be established for the offices and OLA to act on committee requests for documents or (2) revised due dates be negotiated if FDA is unable to meet those specified by committees. However, OLA officials told us that OLA's general policy and practice is to establish internal target dates and to attempt to negotiate revised due dates with committees, although this is not always done.

FDA officials told us that the Centers try to retrieve and forward requested documents to OLA as soon as possible, generally, within 3 to 7 days after receipt of the request. One Center official told us that Centers are often pressured by the Congress and industry to perform FDA's primary duties—program responsibilities—quickly; therefore, the Center tries to respond to requests as soon as possible, but with the least disruption to primary duties. OLA officials told us the Centers are generally prompt in providing documents to OLA; however, officials had no records indicating the Centers' response times.

OLA, in August 1986, developed a form to record the time staff spend working on document requests. This form specifies the dates by which the Centers are requested to provide documents to OLA. OLA officials said, however, that OLA has no authority to require the Centers (or any other offices) to meet these internal target dates.

OLA officials told us that it is OLA's policy to provide the documents to committees as soon as possible. It is FDA's policy to send interim letters, within 6 working days, to the committee if FDA is unable to respond by the committee's specified date. FDA's interim letters acknowledge receipt of the request, but do not offer to negotiate a revised date; in addition, the letters usually do not inform the committee of the date when FDA will provide the documents or the reasons for any delays. According to OLA officials, OLA attempts to negotiate revised dates by phone; however, these negotiations are sometimes not documented. OLA officials attributed its inability to meet committee due dates to other work responsibilities and the number and complexity of requests. These officials stated that document requests are frequently received when OLA is preparing for hearings, responding to other congressional committee or member requests, preparing responses to complex or technical inquiries, and dealing with emergencies and crises. During such periods, officials said, available staff time must be divided among all these activities.

OLA prepares a weekly status report on priority correspondence, which includes committee document requests. This report indicates the dates

the requests are due as well as their status. Although the status reports may show that FDA's responses are overdue, OLA officials told us they do not try to expedite the documents unless the response is considerably overdue or of a particularly time-critical nature, such as documents for hearings. According to OLA officials, OLA professionals are responsible for (1) determining the reasons for delays and (2) attempting to complete the response in the shortest time possible. Other work priorities in OLA and the Centers, however, often hinder these efforts and thus some documents are delayed for fairly long periods.

Conclusions

FDA could improve its response time to requests by providing written guidance to the offices involved and by performing administrative tasks more efficiently. To prevent offices from shifting their copying and trade secret review responsibilities to OLA, the responsibilities for handling requests should be clearly defined. FDA could also improve its response time by eliminating the practice of having OLA review the reasonableness of all trade secret determinations made by the Centers. Because the Centers are considered the experts in making these determinations, greater reliance should be placed on the Centers for properly making them.

FDA's establishment of and adherence to internal target dates for each office to respond to requests would enable FDA to determine its ability to meet committees' due dates. In those cases where FDA is not able to meet these dates, it should advise committees of the reasons and attempt to negotiate a revised due date. These discussions and any agreements reached should be documented in OLA's files.

FDA's practice of documenting information provided to committees—making two sets of copies and a listing of the documents—is time-consuming and sometimes delays the completion of responses. We believe FDA should make both sets of copies at the same time rather than sometimes having one set copied at one time and the second at a different time. When the completion of the listings would prevent FDA from meeting the agreed-to-target date, FDA could prepare the listing after the documents are provided to the committee chairmen. This listing could be prepared from the set of copies retained by OLA and later provided to the committee chairmen and ranking minority members.

Recommendations

We recommend that FDA:

- Provide written guidance to OLA and other FDA offices on their roles and responsibilities for responding to congressional committee requests for documents. Such guidance should include a requirement that two sets of copies of requested documents be made at the same time.
- Direct OLA to not delay providing documents to the requester due to reviewing and questioning trade secret determinations made by the Centers.
- Require OLA to notify committees of reasons for delays, and attempt to negotiate a revised due date when necessary. A record of these contacts should be made in OLA's files, including agreements reached.
- Require OLA to establish internal target dates for offices to meet in carrying out their responsibilities; require the Centers and other offices to either adhere to target dates or inform OLA of the reasons for any delays.
- Require OLA to release documents by the agreed-to-due date in cases where documents would be delayed because the listing has not been completed. (As mentioned earlier, this listing could be prepared from the set of copied documents retained by OLA.) Alert the committees and the ranking minority members that the listing is being prepared and will be provided later.

Agency Comments and Our Evaluation

In February 1987, FDA provided comments on a draft of this report. It agreed with two of the five recommendations FDA said it will do the following: (1) provide written guidance for future use to OLA, FDA Centers, and other offices on their roles and responsibilities for responding to congressional committee requests for documents and consider including a statement in their guidelines concerning the copying of documents; and (2) require OLA staff to notify committees of reasons for delays and attempt to negotiate revised due dates when necessary. FDA said that although revised due dates have frequently been negotiated in the past, there has been no formal requirement to do so, nor has there been a requirement to document any agreements reached. FDA said that OLA staff, if unable to meet committee due dates, will be required to seek revised due dates from the committee.

FDA stated that it would not be practical to provide the Centers with written guidelines for identifying trade secret information, as we had proposed in our draft report. In addition, FDA said that it has been OLA's practice to set internal target dates, but FDA believed a requirement that

the dates be met would not be in the public's interest. Furthermore, FDA said that it is not acceptable to release documents without the listing.

Concerning written guidelines for the Centers to use in identifying trade secret information that should not be released to the public, FDA stated it has a regulation (21 C.F.R. 20) that provides guidance as to what constitutes a trade secret, both by defining "trade secret" in general terms and by referencing specific categories of FDA records. FDA believes the regulation is comprehensive and provides adequate guidance to allow the Centers to make valid judgments concerning what constitutes a trade secret.

As stated in our report, OLA believes all trade secret determinations must be reviewed by OLA for reasonableness because the Centers have a tendency to withhold more information than considered necessary. In the draft report, we proposed to minimize OLA's review of the trade secret determinations made by the Centers, which are considered the experts in their various fields. In instances where OLA questions the Centers' determinations, the release of documents is delayed until the questions have been resolved. In view of FDA's comments (that guidance to the Centers for identifying trade secrets is adequate) on our draft report proposal, we are now recommending that OLA be instructed to not delay providing the documents to the requesters when it questions the Centers' trade secret determinations. Any questions OLA has about whether the Centers have deleted material that is not trade secret can be resolved later.

With regard to establishing internal target dates and assuring that they are met, FDA said that these dates must be flexible if the important functions of FDA are to be fulfilled in a manner commensurate with sound public health interests. According to FDA, document requests are only one of several major workloads generated by the Congress. It said often the same people in the Centers are involved in responding to requests for assistance or information at the same time that they are working on matters of great public health significance—reviewing new drugs or devices, taking regulatory action against potentially dangerous products, reviewing investigational new drugs before testing on humans, and reviewing food-additive petitions.

FDA stated its practice has been to set internal target dates for its Centers and other offices, but there has been no requirement that the target dates be met. In our draft report, we noted that FDA recently developed a form that includes information on internal target dates for the Centers. This form, however, does not establish targets for the other offices

involved in processing requested documents. Internal target dates for the other offices are generally communicated orally. These dates were not always indicated in OLA's weekly status report; therefore, we could not verify that they had been established. We believe keeping a record of the internal target dates established for the other offices would help FDA in determining whether the offices are major contributors to delays.

In making our recommendation, we recognized that it may not always be possible to meet committees' due dates; therefore, we included a provision that the Centers and offices should inform OLA of the reasons for any delays. This information should be helpful to OLA in negotiating revised due dates with the committees. We believe an agency-wide requirement that internal target dates be met would better assure the prompt completion of the responses.

Concerning our recommendation that FDA release documents before preparing a list, FDA stated that the list assists FDA staff in responding to committee questions about the documents. FDA said that, without lists, committee staffs would review the documents without having an acceptable way of referencing specific documents when making inquiries. Before initiating the lists, FDA said its staff, whenever asked, spent significant amounts of time trying to locate the exact document in question. In addition, FDA frequently had to supply duplicates of documents because identification of the documents provided was so inexact that neither FDA nor the requester could be sure a specific document had been sent.

We believe that FDA should not delay providing documents that have been copied and are available for delivery, except for the listing. In such cases FDA could provide the requested documents and then prepare the listing in sufficient time to respond to questions about the documents. If necessary, FDA could devise a method to facilitate identification of documents before the listing is prepared, such as indexing or numbering each copy of the document provided to the committee as well as the copy retained by OLA.

Comments From the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date February 5, 1987

From Commissioner of Food and Drugs

Subject FDA Comments on the Draft GAO Report Entitled "Food and Drug Administration: Response Time to Congressional Committee Document Requests Can Be Improved"

To David P. Baine
Associate Director, Human Resources Division

We have reviewed the subject GAO draft report and in the interest of accuracy prepared a marked-up copy for your consideration. In addition, we have the following comments about the recommendation.

RECOMMENDATION 1

Provide written guidance to OLA and other FDA offices on their roles and responsibilities for responding to Congressional committee requests for documents. Such guidance should include a requirement that both sets of requested documents be copied at the same time.

FDA COMMENT

While we believe that OLA and other FDA offices are aware of their roles and responsibilities with regard to responding to Congressional committee requests for documents, we agree to provide written guidance for future use.

As we pointed out in our discussions with the auditor, our usual practice already is to make both copies of requested documents at the same time. Instances where this has not been done are aberrations from the normal procedures and occur only occasionally. We will consider including a statement regarding copying documents in the guidelines when they are drafted.

RECOMMENDATION 2

Provide written guidelines to the Centers to help them identify trade secret information.

FDA COMMENT

FDA has a published regulation (21 CFR, Part 20) regarding the release of information to the public. The regulation provides guidance as to what constitutes a trade secret, both by defining "trade secret" in general terms and by referencing specific categories of Food and Drug Administration records. We believe the regulation is comprehensive and provides ample guidance to FDA components to allow them to make valid judgments regarding what constitutes a trade secret.

It should be noted that identification of trade secret information must ultimately be done on a case-by-case basis by an individual who is familiar with both the regulations and the subject matter in question. Since FDA's responsibilities cover a broad range of subjects, processes, formulae, etc., it is impractical to be more specific.

RECOMMENDATION 3

Require OLA to notify committees of reasons for delays and attempt to negotiate a revised delivery date when necessary. A record of these contacts should be made in OLA's files, including agreements reached.

FDA COMMENT

We agree. While revised delivery dates have frequently been negotiated in the past, there has been no formal requirement to do so, nor has there been a requirement to document any agreements reached. In the future, OLA staff will be required to seek a new due date from Congressional requesters as necessary. The policy will be so stated in the guidelines discussed above.

RECOMMENDATION 4

Require OLA to establish target dates for offices to meet in carrying out their responsibilities and require Centers and other offices to either adhere to target dates or inform OLA of the reasons for any delays.

FDA COMMENT

It has been OLA's practice to set target dates for FDA component offices in responding to Congressional requests for documents. There has not been an absolute requirement that the target dates be met, nor do we believe such a requirement would be in the public interest. While we currently give a high priority to fulfilling document requests from Congress, other FDA functions must often take precedence when the public health is at stake. Furthermore, document requests are only one of several major workloads generated by the Congress. Other congressionally generated activities that must be integrated into FDA's workload include coordination of investigations, preparation of testimony, responses to lengthy questionnaires, and numerous telephone and written Congressional inquiries on behalf of constituents. Often the same people in the Centers are involved in responding to all these requests for assistance/information at the same time they are working on matters of great public health significance--reviewing new drugs or devices, taking regulatory action against potentially dangerous products, reviewing investigational new drug/device exemption applications for safety prior to testing in humans, reviewing food additive petitions, etc. We will continue to set target dates for receipt of documents from FDA components with the full knowledge that

these dates must be flexible if the very important functions of FDA are to be fulfilled in a manner commensurate with sound public health interests.

RECOMMENDATION 5

Requires OLA to release documents by the agreed to date in cases where documents would be delayed because the listing has not been completed. This listing could be prepared from the set of documents retained by OLA. Alert the committees and the Ranking Minority Members that the listing is being prepared and will be provided later.

FDA COMMENT

We disagree. The listing is an index of the various documents, whose primary purpose is to assist FDA staff in responding to Congressional questions regarding those documents. Our experience prior to initiating the practice of preparing the lists was that Agency staff were spending significant amounts of time trying to locate the exact document in question whenever asked. We also frequently had to supply duplicates of documents merely because identification of the documentation provided was so inexact that neither we nor the requestor could be sure a specific document had been sent. This procedure was very inefficient and confusing to all concerned. We believe that forwarding documents to a requester without the index would once again result in that unacceptable situation. Committee staffs would begin to review the documentation without having an acceptable way of referencing specific documents when making inquiries.

If we can be of assistance to you or provide further insights into our position regarding the draft report, please call Ms. Lois P. Adams (443-4116).

Frank E. Young, M.D., Ph.D.

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