Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Device Evaluation
Office of the Director

Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to Docket No. 01D-0297, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Additional Copies

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Introduction

This document provides guidance to staff of the Center for Devices and Radiological Health (CDRH) and to industry whose device is the subject of open or partially open advisory committee meetings. The Federal Advisory Committee Act (the FACA) generally requires FDA to make available to the public the information given to panel members except for material that is exempt under the Freedom of Information Act (the FOIA). This guidance describes the process CDRH intends to follow when making this information publicly available. This guidance also describes how these materials should be assembled and timeframes for their availability.

Who should use this guidance?

CDRH staff and industry sponsors, applicants, and petitioners (referred to collectively as "sponsors") who are involved in the development, preparation, or submission of materials given to panel members that are intended for discussion at open public meetings held by CDRH.

How should I use this guidance?

Use this guidance to develop, prepare, and submit panel packages for public release. Panel packages consist of information prepared by industry sponsors and CDRH that brief panel members for upcoming meetings. This document helps ensure that panel packages will be made available as provided under Section 10(b) of the FACA. This guidance also provides information on how to identify information that is exempt from public disclosure under the FOIA and provides timeframes so that the preparation and disclosure process for information to be discussed at an open public meeting is as efficient as possible. CDRH has drafted this guidance to be consistent with the principles and timeframes discussed in "Guidance for Industry and FDA Staff: Guidance on Amended Procedures for Advisory Panel Meetings," issued January 26, 1999 and updated July 22, 2000.

Background

FACA provides that materials that are made available to an advisory committee shall also be made available to the public, if the materials are not exempt from disclosure under the FOIA.

FDA construes the FACA to require that, with respect to any open advisory committee meeting convened pursuant to the FACA, whenever practicable and subject to any applicable exemptions of the FOIA (5 U.S.C. § 552), those materials that are provided to the members of an advisory committee in connection with that meeting must be made available for public inspection and copying before or at the time of the advisory committee meeting.

CDRH has developed a process to make materials provided to advisory committee members in connection with open public meetings available for public disclosure before or at the time of the meeting. This process also ensures that those materials exempt from disclosure under the FOIA are protected. This guidance is designed to minimize the time and resources spent in reviewing, redacting (the deletion of non-disclosable information), and publishing this information. This is so panel meetings can proceed when they are scheduled and comply with the requirements of the FACA.

What is the FACA?

The FACA is a Federal law that establishes a system governing the creation and operation of advisory committees in the Executive Branch of the Federal Government. Section 10(b) of the FACA states that documents made available to advisory committees shall also be available to the public unless the materials are exempt from disclosure under the FOIA. Court decisions interpreting this provision require that, whenever practicable, the public be given access to these disclosable materials before or at the time of the meeting.

What is the FOIA?

The FOIA is a Federal law that establishes a system for making Federal Government records available to the public. The FOIA has nine exemptions to protect certain "exempt" information from otherwise mandatory public disclosure. The exemptions that generally apply to information prepared for advisory committees are:

a. Exemption for trade secret and confidential commercial or financial information.
b. Exemption for information in personnel, medical, and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy (i.e., personal privacy information); and,
c. Exemption for inter-agency or intra-agency memoranda, letters, or communications that are both pre-decisional and deliberative in nature (i.e., deliberative process materials).

Because the Agency believes that sponsors preparing their packages for public disclosure need to be aware of what constitutes a trade secret or what information is considered to be confidential commercial information, we include guidance to explain these terms. Most sponsors recognize

that they should not include personal identifiers in the records they submit to FDA, and FDA will continue to protect personal privacy information from public disclosure in those instances where the sponsor includes such information in its submissions. With respect to information protected by the FOIA's deliberative process privilege, the Agency has discretion to either withhold or disclose such information. Although the pre-decisional memoranda that FDA sends to the panel members often qualify for such protection, the Agency intends to make these memoranda available to the public in most circumstances.

What is a trade secret?

A trade secret is a commercially valuable plan, formula, process, or device that is used for making, preparing, compounding, or processing trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process. (See 21 CFR 20.61(a)) Examples of trade secrets may include device constituents that are not easily identifiable, manufacturing processes, quality control procedures, sterilization techniques, formulas, and schematics or circuit diagrams that are not in the device labeling or otherwise publicly available.

What is confidential commercial information?

The FOIA exemption for confidential commercial information protects information that is related to a business or trade and is confidential. Whether confidential commercial information meets the definition of confidential depends on the circumstances under which the information was submitted to FDA. In the case of information that is required to be submitted to FDA (e.g., to obtain FDA approval or clearance of a device), such information is "confidential" if its disclosure is likely to either cause substantial harm to the competitive position of the submitter or impair the government's ability to obtain reliable information in the future. In cases where the submitter provided the information to FDA voluntarily (e.g., it was not required for approval or clearance) it is "confidential" if the information is of a type that the submitter would customarily not release to the public. Examples of confidential commercial information may include sales statistics, research data, technical designs and drawings, customer and supplier lists, profit and loss data, overhead and operating costs, and financial information.

Note: Information shared with members of the public cannot be considered trade secret or confidential commercial information. This includes circumstances such as where data or information has been filed in a patent, provided to stockholders, published in journals, presented at a symposium or trade show, or made available to the public at a website or upon request.

What is personal privacy information?

There is a FOIA exemption that protects information about an individual when the disclosure of such information "would constitute a clearly unwarranted invasion" of that person's personal privacy. Personal privacy information includes such things as names or other information that would identify patients or research subjects in any medical or similar report, test, study or other research project. In addition to an individual's name, other examples of personal identifiers might include initials, social security numbers, dates of birth and death, identification numbers (such as those assigned by health care providers), addresses, telephone/fax numbers, e-mail

addresses, insurance company names and account numbers. In most instances, the FOIA exemption for personal privacy information would not protect an individual's gender, age, or diagnosis from disclosure because such information is usually not attributable to any specific individual. If a record identifies the relative of the patient, it may be appropriate to redact (delete) certain information about the relative to the extent that such information could reveal the identity of the patient.

What are deliberative process materials?

This FOIA exemption for deliberative process materials protects inter-agency (between FDA and another Federal government agency) or intra-agency (within FDA) pre-decisional memoranda or documents that were written as part of FDA's deliberative process. Examples of such materials include drafts, opinions, and recommendations made before the Agency has issued an order regarding the approval or clearance of a device. Materials protected under this exemption remain exempt even after the decision at issue has been made. FDA has discretion to withhold information that could be protected under this exemption. However, CDRH generally intends to disclose to the public any deliberative process information that is sent to the panel members, including CDRH questions for the panel, review memoranda, proposed slide presentations, panel reviews and primary panel reviewer memoranda. CDRH will remove any trade secret, confidential commercial information, or personal privacy information from these records before they are made publicly available.

How does this guidance relate to the confidentiality provisions governing devices?

Device premarket submissions such as premarket approval applications (PMAs), PMA supplements, premarket notifications [510(k) s], and device classifications and reclassifications are among the topics discussed at open or partially open advisory committee meetings convened by CDRH. FDA has put in place regulations designed to protect information in these submissions that is exempt under FOIA from premature disclosure. (21 CFR § 807.95 [510(k)s]; 814.9 (PMAs and PMA supplements); and 860.5 (classifications and reclassifications)). Although FACA generally requires that, whenever practicable, materials provided to members of an advisory committee in connection with an open meeting must also be made available to the public before or at the time of the meeting, this requirement is subject to the exemptions available under FOIA, including the exemption for confidential commercial information. FDA interprets its regulations governing the confidentiality of information in device premarket submissions to be consistent with the FACA, and will exercise its discretion under the applicable confidentiality regulations in a manner consistent with the FACA and the FOIA statutes.

In general, summaries of safety and effectiveness data will be disclosed because such summaries generally do not constitute confidential commercial information under FOIA. Although some other advisory committee materials relating to the premarket review process might be considered confidential commercial information at earlier stages of the device development process, CDRH believes that it is appropriate under §814.9(d)(1) to make them available at the time of an advisory committee meeting if they are directly relevant to the issues being discussed at the meeting. In general, these materials are often necessary to permit consideration of the safety and effectiveness of a pending application by the advisory committee and are routinely discussed by the advisory committee and the sponsor at open advisory committee meetings. Sponsors of

applications generally know that when their applications go before an open advisory committee meeting, certain information contained in their submissions that might otherwise be nonpublic will often be the subject of open public discussion.

As part of its effort to comply with the FACA and implement this guidance effectively, CDRH also intends to begin including the type of device and name of the company in its Federal Register notices announcing CDRH open public advisory committee meetings.

Medical Device Advisory Committee[1] Meetings

What are open public meetings?

This refers to all portions of panel meetings open to the public. An open public meeting includes CDRH and sponsor presentations, committee deliberations, committee recommendations, and open public hearings. The open public hearing, sometimes referred to as an open public session, is a specific amount of time (usually 1 hour) on the agenda for public attendees to make a presentation to the panel.

What are closed meetings?

This refers to meetings that are closed to public attendance. No advisory committee meeting shall be entirely closed (21 CFR §14.27). However, portions of meetings are ordinarily closed to allow the panel to receive information exempt from disclosure or to conduct pre-decisional deliberations about matters that the FDA determines should be done in a closed portion of the meeting. This guidance does not apply to information discussed at closed committee meetings.

What topics are discussed at CDRH advisory committee meetings?

Device premarket submissions such as original PMAs, PMA supplements, 510(k)s, and reclassification petitions of medical devices, guidance documents and device classifications frequently are topics discussed at advisory committee meetings. In addition, CDRH may convene advisory committee meetings to discuss clinical, scientific, and policy issues related to medical devices, radiological health, mammography, and CDRH's medical device regulatory programs.

What about other submissions, such as PDPs or IDEs?

Device product development protocols (PDP) and IDE submissions may also be the subject of a panel meeting. However, these types of submissions are usually discussed in the closed portion

[1] This guidance applies to the panels of the Medical Devices Advisory Committee: Anesthesiology and Respiratory Therapy Devices Panel; Circulatory System Devices Panel; Clinical Chemistry and Clinical Toxicology Devices Panel; Dental Products Panel; Medical Devices Dispute Resolution Panel; Ear, Nose, and Throat Devices Panel; Gastroenterology and Urology Devices Panel; General and Plastic Surgery Devices Panel; General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Immunology Devices Panel; Microbiology Devices Panel; Molecular and Clinical Genetics Panel; Neurological Devices Panel; Obstetrics and Gynecology Devices Panel; Ophthalmic Devices Panel; Orthopedic and Rehabilitation Devices Panel; and, Radiological Devices Panel. This guidance will apply to future CDRH advisory committees that are chartered and convened.

of a panel meeting because they are more likely to involve deliberations about trade secret and confidential commercial information.

What about combination products?

Combination products may be composed of any combination of a device, drug,[2] or biological[3] product. Under section 503(g) of the Food, Drug, and Cosmetics Act (the act), FDA must designate a Center within FDA to have primary jurisdiction over the premarket review. The policy and procedures described in this guidance apply to any open panel meetings convened by CDRH where CDRH has primary jurisdiction over the product.[4]

Public Availability of Panel Packages

When will information be available to the public?

Whenever practicable, CDRH intends to make the publicly available version of the panel packages available to the public *one business day*[5] before the panel meeting is scheduled to occur.

How will CDRH disclose this information?

Whenever practicable, CDRH will provide the publicly available sponsor panel package, the CDRH background panel package, and meeting handouts to Dockets Management Branch. Dockets Management will release the information *one business day* before the panel meeting. Dockets Management has a Dockets Reading Room where information may be viewed and reproduced. The hours of operation for the reading room are Monday through Friday, 9:00 a.m. to 4:00 p.m. The location is Dockets Management Branch, 5630 Fishers Lane, Room 1061, Rockville, Maryland 20857.

Dockets Management will post the information on the Agency's website, and CDRH encourages sponsors to submit electronic versions of their packages to facilitate posting on the agency's website. Check first with CDRH about compatible electronic formats. Dockets Management web address is: http://www.fda.gov/ohrms/dockets/ac/acwhatsnew.htm

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[2] For guidance applicable to meetings convened by CDER, please consult *Disclosure of Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research,* beginning on January 1, 2000. This document is available from the Drug Information Branch (HFD-210), CDER, 5600 Fishers Lane, Rockville, MD 20857, (Tel) (301) 827-4573, http://www.fda.gov/cder/guidance/index.htm.

[3] For guidance applicable to meetings convened by CBER, please consult *Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologics Evaluation and Research,* beginning on June 1, 2001. This document is available from the Office of Communication, Training and Manufacturers Assistance, HFM-40, CBER, 1401 Rockville Pike, Rockville, MD 20852, http://www.fda.gov/cber/guidelines.

[4] When a combination product over which CDER or CBER has primary jurisdiction is the topic of an open advisory committee meeting convened by one of those two Centers, the device component of the product, if any, will be subject to the disclosure procedures set forth by those Centers (see preceding two footnotes).

[5] A business day means a day that FDA is officially open for business.

Panel Packages

What types of information are sent to the panel?

CDRH identifies the information it believes should be sent to panel members for their review.[6] This information usually includes portions of the sponsor submission and documents generated by CDRH. Before a panel meeting, CDRH asks the sponsor if it would like to include any additional information. The package differs from meeting to meeting and the contents and amount of information included depend upon the type of device or issue(s) to be discussed. The package usually contains some materials that are exempt from disclosure.

Before each advisory committee meeting, CDRH generally provides advisory committee (panel) members two packages of material, usually one from the sponsor and one from CDRH. The two sets of documents may include portions of the following types of information:

Sponsor Panel Package

1. Sponsor Summary of Safety and Effectiveness Data
2. A description of device functions, mechanics, engineering
3. A description of physical characteristics and performance parameters
4. Non-clinical laboratory protocols and raw data
5. Clinical protocols and raw data
6. Statistical protocols and analyses
7. Proposed labeling for the device
8. Information about packaging/sterilization
9. A bibliography of relevant literature citations and references
10. Data, data collection forms, patient data and information
11. Sponsor amendments and responses to CDRH correspondence
12. Sponsor presentations and available slides

CDRH Background Panel Package

1. CDRH correspondence with the sponsor
2. CDRH preliminary reviews and memoranda
3. Panel reviews/primary panel reviewer memoranda (if available)
4. CDRH questions for the panel
5. CDRH presentations and available slides
6. Presentations from members of the public (if available)
7. Guidance documents (if relevant)

[6] A panel primary reviewer may be assigned to conduct a comprehensive and focused analysis of the data found in a submission. In many cases, the panel primary reviewer may receive material that differs from what is generally sent to the entire panel. When a panel primary reviewer is utilized, the preparation of the panel primary reviewer's package typically begins earlier than preparation of the full panel package, perhaps eight to ten weeks before the scheduled panel meeting. CDRH will notify the sponsor if a panel primary reviewer will be assigned so that the panel primary reviewer's package can be prepared. This guidance applies to information given to the entire panel.

Exempt information will be redacted from all parts of the panel packages before the information is made available to the public. See below.

What information in the panel package does CDRH generally consider available for public disclosure?[7]

CDRH believes the following information found in the sponsor's panel package and the CDRH background panel package may generally be released to the public as appropriate without redaction:

Sponsor Panel Package

1. Summaries of Safety and Effectiveness
2. Summaries of non-clinical laboratory studies
3. Summaries of clinical studies involving human subjects
4. Summaries of statistical analyses of the studies
5. Clinical, preclinical, and statistical protocols
6. Proposed labeling for the device
7. Bibliographies of relevant literature citations and references
8. Sponsor presentation and available slides

CDRH Background Panel Package

1. CDRH preliminary reviews and memoranda
2. Panel reviews/panel primary reviewer memoranda (if available)
3. CDRH questions for the panel
4. CDRH presentations and slides
5. Presentations from members of the public (if available)
6. Guidance documents (if relevant)

These lists are neither exhaustive nor absolute and should be considered broad guidance to aid sponsors in their submissions and CDRH in its preparation and review of panel packages.

What information in a panel package does CDRH generally consider exempt from public disclosure?

Ordinarily, the following information is considered trade secret or confidential commercial information exempt from public disclosure:

1. Information about device functions, mechanics, engineering, and schematic drawings not in the proposed labeling
2. Proprietary physical characteristics and performance parameters not in the proposed labeling
3. Device good manufacturing practice (GMP) information (if different from what is standard in the industry).
4. Manufacturing quality control information.

[7] If the panel is meeting to consider a reclassification petition, the entire panel package will be available to the public because the petition and all supporting materials are filed at our Dockets Management Branch when they are submitted to FDA.

5. Non-clinical raw data.[8]
6. Clinical raw data.
7. Supplier names, customer lists, production costs, inventory, failure rates of devices, device production quality control (QC).

This list is neither exhaustive nor absolute and should be considered broad guidance to aid sponsors in their submissions and CDRH in its preparation and review of panel packages.

What are the timeframes for this process?

Approximately *eight weeks* before an advisory panel meeting, CDRH notifies the sponsor that the submission is going to panel. CDRH encourages sponsors to begin working with the panel's Executive Secretary to prepare its panel packages as early as feasible. However, CDRH notes that if the preparation of the panel package occurs too early, the package may not adequately address all of the issues discussed at the panel meeting, because those issues might not yet be fully developed.

At the end of this guidance are two tables. The first table projects an estimate of the amount of time needed for review, redaction, and final preparation of sponsor panel packages that contain trade secret and/or commercial confidential information. This table outlines how FDA will make available this type of a package for public release. The other table projects an estimate of the time needed for a package that the sponsor indicates is fully releasable to public without any redactions.

CDRH notes that the timelines do not provide for formal predisclosure notification to sponsors pursuant to 21 CFR 20.61(e) and (f). The predisclosure notification requirements in that section apply only where the disclosure is to be made in response to a specific request for Agency records. The disclosures contemplated here are not made in response to such a request, but to comply with the FACA.

This guidance document constitutes public notice under 21 CFR 14.35(d)(2) that a sponsor package should be submitted within the timeframes described if it is to be considered by an advisory committee convened by CDRH. If a submission from a sponsor is not received by CDRH within the timeframes listed, it will not be forwarded to the committee and will not be considered by the committee.

Preparation of Sponsor Panel Packages

How will the sponsor prepare its panel package?

Approximately *eight weeks* before a meeting, CDRH will notify the sponsor and identify materials that CDRH believes should be included in the sponsor panel package. CDRH will ask

[8] For the purposes of this guidance, CDRH considers "raw data" to be a complete data set of case report forms, case report tabulations, or line listings. Data that summarize individual or multiple subject outcomes or results are considered summaries. Summaries may include examples of specific findings.

the sponsor if any additional information should be included. The sponsor will collate the materials CDRH has requested and additional information the sponsor wants to include and submit it as the "sponsor panel package."

What if the sponsor chooses to prepare a fully releasable panel package?

The sponsor may elect to prepare a fully releasable panel package. In other words, the sponsor panel package does not contain information that the sponsor believes is exempt from disclosure under the FOIA. CDRH will review this package for completeness and relevance. This package can be fully released to the public without redaction. If the sponsor chooses this option, the package should be clearly marked:

"Panel Package: Available for Public Release"

Because this type of sponsor panel package will not need agency redaction for trade secret and confidential commercial information, it may be submitted to CDRH closer in time to the panel meeting than a package that requires redaction. This gives the sponsor more time to prepare its submission.

What if the sponsor chooses to prepare a panel package that contains information that it believes is not available for public release?

The sponsor may elect to prepare a panel package that contains trade secret and/or commercial confidential information. In other words, the sponsor panel package contains information that the sponsor believes is exempt from disclosure under the FOIA. If the sponsor chooses this option, the final package should be clearly marked:

"Draft: Contains Trade Secret and/or Confidential Commercial Information: Not for Public Release"

At the same time, the sponsor should prepare and submit another copy of the *same* material *redacted* of confidential/trade secret information. The document should be prominently labeled:

"Draft: Panel Package: Available for Public Release"

CDRH will review the unredacted sponsor's package for completeness and relevance. CDRH will review the redaction version to determine if exempt information has been identified appropriately. CDRH will discuss any disagreements about disclosability with the sponsor. When the discussions are concluded, CDRH will notify the sponsor of its final decision. When the sponsor receives CDRH's notification, the sponsor will make revisions as appropriate and submit a final copy of both documents. The final documents are to be prominently labeled as: **"Final: Contains Trade Secret and/or Confidential Commercial Information: Not for Public Release"** and **"Final: Panel Package: Available for Public Release,"** respectively.

CDRH cautions that submissions should include only information that accurately reports data that support the application and are directly relevant to the issues discussed at the meeting. Statements or suggestions that could be viewed as misleading or promotional (e.g., statements

that go beyond the study conclusions or speculate about clinical or commercial implications not supported by the data or not the subject of the panel meeting) are inappropriate for inclusion in the package.

When this process is complete, CDRH will send the unredacted version of the sponsor panel package to the panel members to review in preparation for the scheduled meeting.

Will sponsors have an opportunity to comment on the CDRH background panel package?

Yes. The Center will send the sponsor a copy of the "CDRH background panel package" and discuss any disagreements the sponsor may have about the disclosability of information in that package. When discussions are concluded, CDRH will notify the sponsor of its final decision.

What can a sponsor do if it cannot resolve a disagreement with CDRH about what information is disclosable?

If discussions between CDRH and the sponsor fail to result in an agreement about what is lawfully exempt from disclosure, the sponsor will have an opportunity to seek judicial review of the Agency's determination. If a sponsor does file a lawsuit to stop the Agency from disclosing information, the Agency will not release the information until the legal issues are resolved and the panel meeting will be postponed until the decision is final.

How will FDA notify the public that the sponsor's publicly available panel package does not reflect a final Agency decision about the device?

In an effort to avoid any misunderstanding that CDRH endorses the content of the sponsor's panel package by posting it on the Agency website, the following statement will accompany each set of sponsor panel packages placed on the FDA website:

> ***"The statements contained in this document are those of the product's sponsor, not FDA, and FDA does not necessarily agree with the sponsor's statements. FDA has not made a final determination about the safety or effectiveness of the product described in this document."***

CDRH also reserves the right to take appropriate action to address any information that may be promotional or misleading, including posting a correction on the Agency's website.

Will CDRH release other information from the submission as part of this process?

No, the Agency will release only the publicly available sponsor panel package and the publicly available CDRH background panel package before the panel meeting. Other portions of the submission will not be available until after FDA issues an order regarding the approval of the device.

Will the public know if information has been redacted (deleted) from the panel package?

Yes. FDA's policy is for sponsors to call attention to any deletions and to indicate how much material has been redacted. Sponsors may indicate the amount of information that has been removed in several ways. One method is to include a statement such as "two paragraphs have been deleted," or "five whole pages have been removed."

Who actually redacts exempt information from the sponsor panel package?

After the sponsor and CDRH agree on the information to be redacted, the sponsor removes protected information from the panel package and submits the redacted package to CDRH for public release. CDRH asks sponsors to segregate the information in its panel package into separable portions whenever possible: portions that are releasable and portions that are trade secret and confidential. In this way, the redaction process will be easier.

How does the sponsor redact or "purge" a panel package for public release?

Protected information is either removed or completely obliterated. Sponsors may obliterate text by using a black marker or a strip of tape that completely obscures the text. This assures that text cannot be read. If there is a large amount of text to be removed, it can be cut out of the document. Alternatively, sponsors may redact documents using electronic means. Whichever method is used, sponsors must identify the material that has been removed, and note the deletion, e.g., "two pages removed. When this process is complete, the sponsor makes a photocopy of the redacted document and submits it to CDRH.

What else should the sponsor know about redacting its panel package?

On the following page are examples of do's and don'ts regarding this process:

Do

- The following sentence is redacted properly by completely obscuring text: [redacted]

Don't

- The following sentences are not redacted properly because text is either still visible or is not completely obscured from view:
    - Highlighting or marking text is not recommended because text is visible and is not obscured.
    - ~~Using a strike through feature is not recommended because text is still visible.~~

What if I still have questions about redacting my sponsor panel package?

If you still have questions, call, write, or visit the FDA FOIA website below:

Freedom of Information Staff, HFZ-82
Center for Devices and Radiological Health
2094 Gaither Road
Rockville, Maryland 20850
(301) 594-4774, Ext. 128
http://www.fda.gov/cdrh/devadvice/36g1.html

Timeline: Sponsor Panel Packages That Are Not Fully Releasable.

CDRH Action	Time Before the Meeting	Sponsor Action
CDRH notifies the sponsor of the information it believes should be reviewed by the panel.[9] CDRH asks the sponsor whether there is any additional information that it believes should be included in the mailout.	**8 weeks**	
	7 weeks	The sponsor collates and sends the information. The package should be labeled **"DRAFT: CONTAINS TRADE SECRET AND/OR CONFIDENTIAL COMMERCIAL INFORMATION: NOT FOR PUBLIC RELEASE"** The sponsor also prepares and submits to CDRH another copy of the same material redacted of trade secret/confidential commercial information. **"DRAFT: PANEL PACKAGE: AVAILABLE FOR PUBLIC RELEASE"**
CDRH reviews the draft unredacted sponsor materials for completeness and relevance and reviews the draft redacted version of the materials to see if they are properly exempt.	**6 weeks**	
CDRH and sponsor conclude discussions on the contents and public availability of the sponsor's draft panel packages.	**5 weeks**	
	4 weeks	The sponsor sends CDRH a final copy of the package labeled **"CONTAINS TRADE SECRET AND/OR CONFIDENTIAL COMMERCIAL INFORMATION: NOT FOR PUBLIC RELEASE"**and a final copy of **"PANEL PACKAGE: AVAILABLE FOR PUBLIC RELEASE"**
CDRH sends the sponsor's final document **"CONTAINS TRADE SECRET AND/OR CONFIDENTIAL COMMERCIAL INFORMATION: NOT FOR PUBLIC**	**3-4 weeks**	

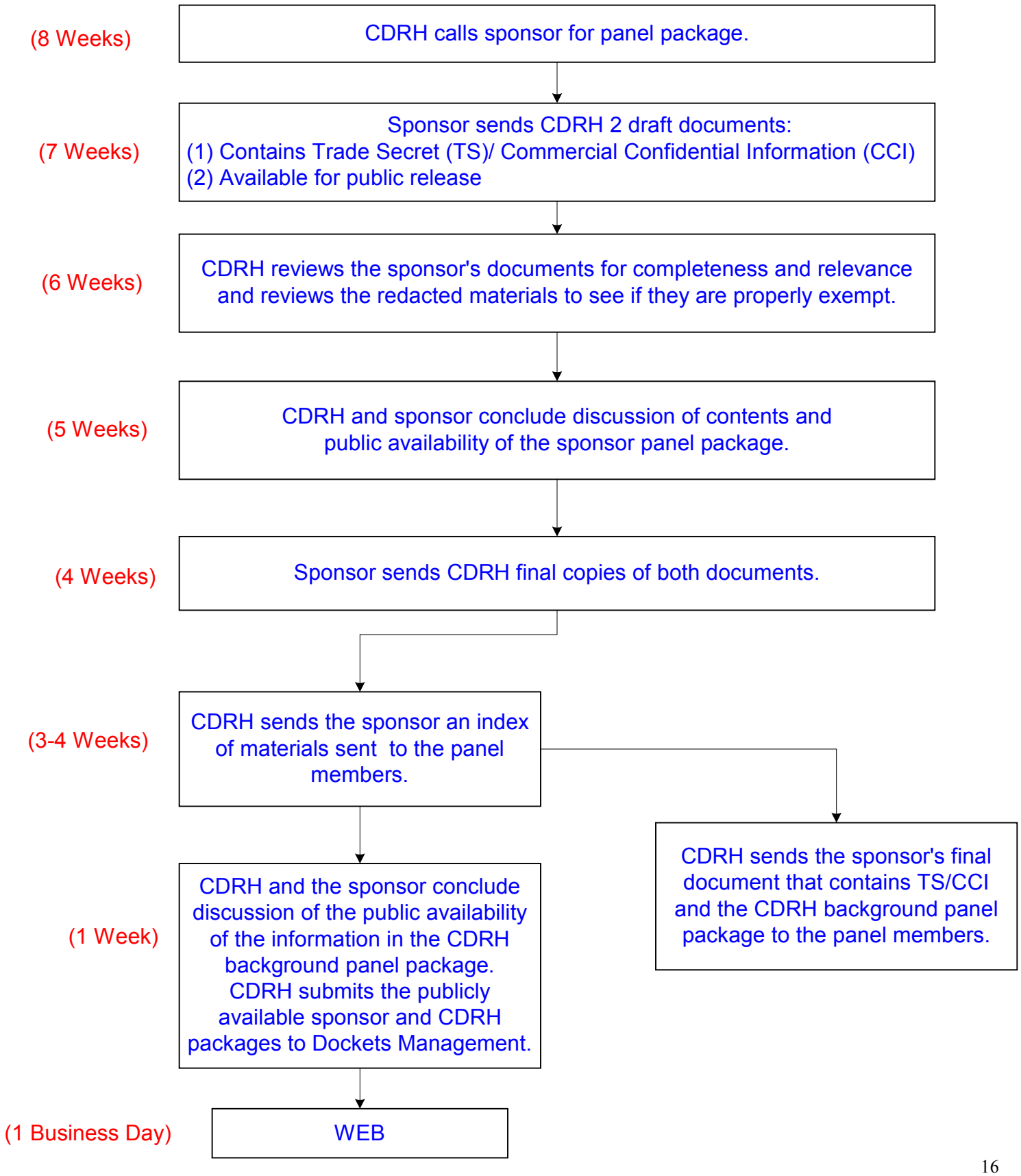
[9] If primary reviewers are assigned, CDRH will begin discussions with the sponsor 8-10 weeks before the scheduled meeting (See Footnote 6).

RELEASE" and the CDRH background package to the panel members and to the sponsor. At the same time, CDRH sends the sponsor ar index of all materials sent to the panel members.		
CDRH and the sponsor conclude discussions concerning the public availability of the information in CDRH's background panel package. CDRH submits the publicly available sponsor and CDRH panel packages to Dockets Management Branch for posting on the Dockets Management website.	**1 week**	
Publicly available materials are posted on the Dockets Management website.	**1 Business Day**	
If CDRH is unable to post the above materials before the meeting, CDRH will make the package available in hard copy at the meeting.[10]	**Day of the meeting**	Sponsors are encouraged to bring a reasonable number of copies of their **"PANEL PACKAGE: AVAILABLE FOR PUBLIC RELEASE"** to the panel meeting for distribution to the public.

[10] Any changes in the presentation or packages that are made at the last minute will be updated on the website following the meeting.

PANEL PACKAGE FLOW CHART

(Sponsor Panel Packages that Are Not Fully Releasable)



Timeline: Sponsor Panel Packages That Are Fully Releasable.

CDRH Action	Time Before the Meeting	Sponsor Action
CDRH notifies the sponsor of the information it believes should be reviewed by the panel. CDRH asks the sponsor whether there is any additional information that it believes should be included in the mailout.	**8 weeks**	
	5 weeks	The sponsor sends CDRH fully releasable materials labeled **"PANEL PACKAGE: AVAILABLE FOR PUBLIC RELEASE"**
CDRH reviews the sponsor materials for completeness and relevance.	**4 weeks**	
CDRH sends the sponsor's document **"PANEL PACKAGE: AVAILABLE FOR PUBLIC RELEASE"** and the CDRH background package to the panel members an to the sponsor. At the same time, CDRH send the sponsor an index of all materials sent to th panel members.	**3-4 weeks**	
CDRH and the sponsor conclude discussions concerning the public availability of the information in CDRH's background panel package.	**1 week**	
CDRH submits the publicly available packages to Dockets Management Branch for posting on the Dockets Management website.		
Materials are posted on the Dockets Management website.	**1 Business Day**	
If CDRH is unable to post the above materials before the meeting, CDRH will make the package available in hard copy at the meeting.[11]	**Day of the meeting**	Sponsors are encouraged to bring a reasonable number of copies of their **"PANEL PACKAGE: AVAILABLE FOR PUBLIC RELEASE"** to the panel meeting for distribution to the public.

[11] Any changes in the presentation or packages that are made at the last minute will be updated on the website following the meeting.

PANEL PACKAGE FLOW CHART

(Sponsor Panel Packages that Are Fully Releasable)