Guidance for Industry

Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of the draft document contact Murray M. Lumpkin at 301-594-5400.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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Procedural

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Additional copies are available from:
Drug Information Branch (HFD-210),
Center for Drug Evaluation and Research (CDER),
5600 Fishers Lane, Rockville, MD 20857 (Tel) 301-827-4573
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U.S. Department of Health and Human Services
Food and Drug Administration
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Draft -- Not for Implementation

Guidance for Industry[1]

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I. PURPOSE

This document is intended to provide guidance to the sponsors of applications that are the subjects of open advisory committee meetings convened by the Center for Drug Evaluation and Research (CDER), beginning January 1, 2000.[2] It describes the procedures CDER intends to follow when making publicly available the information provided to advisory committee members in connection with such meetings. The guidance also describes how a sponsor should prepare its submissions to an advisory committee.

The procedures described in this guidance are intended to make the process of complying with the disclosure requirements of the Federal Advisory Committee Act (the FACA) (5 U.S.C. App. 2) as efficient as possible. These procedures address (1) the content and organization of a sponsor submission for an advisory committee, (2) the timing of the sponsor submission to CDER, (3) the process by which CDER will review and redact the sponsor submission and the related CDER submission, and (4) the effect this process may have on the time allotted to a review cycle in which an advisory committee meeting occurs.

II. BACKGROUND

On November 30, 1999 (64 FR 66920), CDER issued a guidance document on the public disclosure

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[1] This guidance document represents the Agency's current thinking on the implementation by the Center for Drug Evaluation and Research (CDER) of the disclosure provisions of the FACA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

[2] This guidance covers the following advisory committees: Anesthetic and Life Support Drugs, Anti-Infective Drugs, Antiviral Drugs, Arthritis, Cardiovascular and Renal Drugs, Compounding, Dermatologic and Ophthalmic Drugs, Drug Abuse, Endocrinologic and Metabolic Drugs, Reproductive Health Drugs, Gastrointestinal Drugs, Generic Drugs, Medical Imaging Drugs, Nonprescription Drugs, Oncologic Drugs, Peripheral and Central Nervous System Drugs, Pharmaceutical Science, Psychopharmacologic Drugs, Pulmonary-Allergy Drugs. CDER advisory committees that are chartered in the future will also be covered by this guidance.

of materials provided to advisory committees in connection with open advisory committee meetings convened by CDER on or after January 1, 2000 (*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*[3]) (the disclosure policy guidance). In that document, CDER provided the following interpretation of the Agency's responsibilities under the FACA and of FDA's regulations governing disclosure of information concerning new drug applications in 21 CFR 314.430:

> 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 Freedom of Information Act (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. FDA interprets § 314.430 to be consistent with the FACA and therefore will exercise its discretion under § 314.430(d)(1) in a manner consistent with the FACA and the FOIA as described in the previous sentence to make available for public inspection and copying materials provided to the members of an advisory committee in connection with open advisory committee meetings convened by CDER, beginning on January 1, 2000.

CDER will make advisory committee materials available consistent with these principles. CDER has developed procedures for ensuring that materials that are provided to advisory committees in connection with open advisory committee meetings convened by CDER beginning January 1, 2000, will be made publicly available before or at the meeting, whenever practicable. These procedures should also ensure that those materials that are exempt from disclosure under the FOIA will not be made publicly available. These procedures are designed to minimize the time and resources spent reviewing the materials in an advisory committee submission, determining which materials are exempt from disclosure under the FOIA, and redacting such materials.

It is necessary to minimize CDER consultation and redaction time because the more time the Agency needs to redact materials in advance of an advisory committee meeting, the earlier in the application review process the sponsor must prepare its background package for the advisory committee. If the preparation of the advisory committee package occurs too early in the review process, the package may not adequately address the issues that will be the subject of the advisory committee meeting, because those issues will not yet have crystallized.

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[3] 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.

An alternative to setting an earlier date for submission of advisory committee packages to allow for adequate review and redaction time is to maintain the current timing of the submission of the advisory committee package, but postpone the date of the advisory committee meeting until later in the review of the application. This would necessitate, in turn, an extension of the total review time allotted to that review cycle. It is therefore critical to keep to a minimum the period of time spent on the process of reviewing and redacting an advisory committee package.

III. APPLICABILITY OF THE DISCLOSURE PROCEDURES DESCRIBED IN THIS GUIDANCE

Although most advisory committee meetings convened by CDER concern new drug applications (NDAs) or NDA supplements, a few may concern abbreviated new drug applications (ANDAs), biological license applications (BLAs), or premarket approval applications (PMAs) for devices. CDER interprets the disclosure policy guidance to apply to all open advisory committee meetings convened by CDER beginning January 1, 2000, where the focus of the meeting solely or primarily addresses an NDA, NDA supplement, or ANDA. Therefore, if an unapproved BLA or PMA is being discussed at a segregable portion of a CDER advisory committee meeting (for example, during the afternoon session), that BLA or PMA will not be subject to the disclosure procedures described in this guidance. However, if an unapproved BLA or PMA is being discussed in unison with an NDA (for example, a combination product consisting of both a drug and a device), that BLA or PMA will be subject to these disclosure procedures to the extent allowed under applicable law.

The procedures outlined in this guidance do not apply to submissions in connection with open advisory committee meetings that do not concern the approval or testing of products (the type of meetings that involve, for example, postapproval monitoring programs, over-the-counter monograph issues concerning the safety of already-marketed products, or general policy/guidance issues) because the submissions for such meetings do not generally involve as much redaction as submissions for meetings on unapproved products or unapproved new indications for approved products. The procedures in this guidance also do not apply to (1) closed advisory committee meetings and (2) open advisory committee meetings convened solely by components of FDA other than CDER.

IV. ORGANIZATION OF SPONSOR SUBMISSIONS TO ADVISORY COMMITTEES

A. Fully Releasable Sponsor Submissions

To shorten the process of complying with the FACA's disclosure requirements, sponsors are strongly encouraged to submit advisory committee packages that may be publicly disclosed in their entirety (i.e., that do not contain any information that the sponsor asserts is exempt from disclosure under the FOIA

because it is trade secret or confidential commercial information, or because it is information the disclosure of which would constitute an unwarranted invasion of personal privacy, for example by including names or other information that would personally identify individual subjects). Sponsors are also encouraged to submit an electronic version of the package. A submission that is fully releasable (whether hard copy or electronic) should be clearly marked "**AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION**" in uppercase, bolded script. Because such a submission will not require agency redaction for trade secret and confidential commercial information, it may be submitted to CDER closer in time to the advisory committee meeting than a package that requires redaction (see section V). This will give the sponsor more time to prepare the submission.

B. Sponsor Submissions That Contain Material Claimed to be Exempt From Disclosure

If the sponsor believes that it is necessary to include material in an advisory committee submission that it believes is exempt from disclosure under the FOIA, the sponsor should:

1. Segregate the material it believes is exempt from the disclosable material, generally by placing it in a separate portion of the briefing package. Where that is not possible, the material that the sponsor believes is exempt should be designated by a distinct typeface.

2. Clearly designate the material that the sponsor believes is exempt.

3. For each document or portion of a document that the sponsor believes is exempt from disclosure, provide a detailed justification explaining (a) why the information is necessary to the advisory committee's consideration of the issues before it and (b) why the sponsor believes the information is exempt from disclosure under the FOIA.

Sponsors are also encouraged to submit an electronic version of the package. Following these steps will reduce the time CDER must spend determining the exempt status of the materials, consulting with the sponsor, and redacting any such exempt material.

C. What is Typically Disclosable and What is Typically Exempt from Disclosure?

To assist a sponsor in determining which materials in its advisory committee package are likely to be considered disclosable under the FOIA, CDER is providing guidance on certain materials that it is unlikely to consider confidential commercial or trade secret information exempt from disclosure under Exemption 4 of the FOIA.

In general, summaries of safety and effectiveness data will be disclosed. Although full reports of safety

and effectiveness data might be used by a competitor to support approval of a competing product, a summary could not be so used and, therefore, generally does not constitute confidential commercial information.

Although some of the other materials from an application listed below might be considered confidential commercial information at earlier stages of the drug development process, CDER believes that it is appropriate to make them available under §314.430(d)(1) at the time of an advisory committee meeting if they are germane to the issues to be discussed at the meeting. In general, these materials are often necessary to permit consideration of the safety and effectiveness of an unapproved application before an advisory committee and are routinely discussed by the advisory committee and the sponsor at an open advisory committee meeting. Sponsors of applications generally know that when their unapproved applications go before an open advisory committee, the information contained in the materials listed below will often be the subject of open discussion.

Ordinarily, the following materials in advisory committee packages will be considered disclosable, unless they contain information that the sponsor demonstrates will cause substantial competitive harm if disclosed:

1. Summary tables of safety and effectiveness data

2. Summaries of clinical or non-clinical safety or effectiveness data

3. Summaries of suspected adverse drug reaction data

4. Statistical summaries of safety and effectiveness data

5. Clinical or preclinical protocols

6. Copies of slides to be presented by the sponsor at the advisory committee meeting

7. Names of principal investigators

8. Proposed INDICATIONS FOR USAGE, DOSAGE AND ADMINISTRATION, and safety sections of product labeling

9. Any other information that has been previously publicly disclosed by the sponsor

Ordinarily, the following materials in advisory committee packages will be considered trade secret or

confidential commercial information that is exempt from disclosure under the FOIA:

1. Product formulation and other chemistry, manufacturing, and controls (CMC) information

2. Full reports of raw clinical or preclinical data[4]

3. Reports of unpublished studies

These lists are neither exhaustive nor absolute and should be considered broad guidance to aid sponsors in their submissions and CDER in its redaction of advisory committee briefing packages.

Regardless of whether a sponsor submits a package that it designates as fully releasable, CDER cautions that submissions should include only information that accurately reports data that support the application and are directly relevant to the issues being 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 advisory committee meeting) are inappropriate for inclusion in the package. In an effort to avoid any misunderstanding that CDER has endorsed the contents of a sponsor package by posting it on the Agency's website (see section V), the following notice will accompany each set of briefing materials 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." CDER 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.

V. TIMING OF SPONSOR'S ADVISORY COMMITTEE SUBMISSIONS AND CDER REVIEW

CDER has developed the following timelines for submission and redaction of materials provided to CDER advisory committees in connection with open advisory committee meetings convened by CDER to discuss the testing of products or to discuss unapproved applications (including efficacy supplements to approved applications) to market products.

CDER notes that the timelines do not provide for formal predisclosure notification of sponsors pursuant to 21 CFR 20.61(e) and (f). The predisclosure notification requirements in that section apply only

[4] For the purposes of this guidance, CDER considers data to be "raw data" if they are presented by individual subject. Data that summarize or average multiple subject outcomes/results are considered summaries.

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. Nevertheless, the time frames are at least as generous as the time frames for notification of sponsors under 21 CFR 20.61.

This guidance document constitutes public notice under 21 CFR 14.35(d)(2) that a sponsor package should be submitted within the time frames listed below if it is to be considered by a CDER advisory committee.[5] If a submission from a sponsor is not received by CDER within the time frames listed below, it will not be forwarded to the committee and will not be considered by the committee. In the time frames, *business day* means a day that FDA is officially open for business.

A. Fully Releasable Sponsor Submissions

1. By close of business (COB) 22 business days prior to the advisory committee meeting, the sponsor should submit its background package to the CDER Advisors and Consultants Staff (ACS).

2. By COB 21 business days prior to the advisory committee meeting, ACS will send the sponsor package to committee members by overnight mail and to the CDER review division(s).

3. By COB 19 business days prior to the advisory committee meeting, the CDER review division(s) should submit its background package to ACS.

4. By COB 18 business days prior to the advisory committee meeting, ACS will send the CDER background package to the CDER Freedom of Information (FOI) staff for redaction review.

   By COB 18 business days prior to the advisory committee meeting, ACS will send the complete (i.e., unredacted) CDER background package to the committee members by overnight mail.

5. By COB 15 business days prior to the advisory committee meeting, the FOI staff will submit to ACS a redacted version (if any) of the CDER background package.

6. By COB 14 business days prior to the advisory committee meeting, ACS will send to

[5] See footnote 2 for a list of CDER advisory committees.

the sponsor by overnight mail a copy of the redacted version of the CDER background package.

7. By COB 8 business days prior to the advisory committee meeting, final discussions with the sponsor on redaction of exempt materials from the CDER package will be completed.

8. By COB 7 business days prior to the advisory committee meeting, CDER will fax and send to the sponsor by overnight mail a letter stating CDER's final decision on redaction of material from the CDER package.

9. By COB 7 business days prior to the advisory committee meeting, the sponsor package and CDER's redacted package will be submitted by ACS to the Dockets Management Branch for preparation for posting on the FDA website.

10. 1 business day prior to the advisory committee meeting (24 hours prior to meeting), FDA will post on its website the sponsor package and CDER's redacted package. If FDA is unable to post the package on its website prior to the meeting, the two packages will be made publicly available at the location of the advisory committee meeting, and the two packages will be posted on the Agency website after the meeting. Sponsors are encouraged to bring to the meeting, for public distribution, a reasonable number of hard copies of the slides they will be presenting.

B. Sponsor Submissions That Contain Material Designated by the Sponsor as Exempt From Disclosure (Marketing Application is Under Standard Review)

1. By COB 48 business days before the advisory committee meeting, the sponsor should submit to ACS two versions of its background package: a complete (unredacted) version and a redacted version. In the complete version, the material the sponsor believes to be exempt from disclosure should be segregated and clearly marked and should be accompanied by the justification described in section IV above for each document or portion of a document the sponsor asserts is exempt. In the redacted version, the material that the sponsor believes is exempt should be deleted. Three copies of each version of the background package should be submitted to ACS.

2. By COB 47 business days before the advisory committee meeting, ACS will send one copy of the sponsor's submission to the FOI staff and one copy to the appropriate review division(s).

3. By COB 35 business days prior to the advisory committee meeting, CDER will fax and send to the sponsor a letter stating which materials it believes should be redacted from the sponsor package.

4. By COB 30 business days prior to the advisory committee meeting, final discussions with the sponsor on redaction of materials from the sponsor package will be completed.

5. By COB 28 business days prior to the advisory committee meeting, CDER will fax and send to the sponsor by overnight mail a letter stating CDER's final position on redaction of material from the sponsor package. The sponsor then has 5 business days in which to decide whether to remove any materials that CDER has determined will not be redacted if the background package is ultimately submitted for committee review and to reformat the submission accordingly. No new materials for possible redaction may be added to the package during this period.

6. By COB 22 business days prior to the advisory committee meeting, the sponsor's complete and redacted final package FOR ADVISORY COMMITTEE REVIEW should be submitted to ACS. It should be made clear to CDER what materials that were originally in the package have been removed, if any. The sponsor should submit the unredacted package and the redacted package to ACS.

7. By COB 21 business days prior to the advisory committee meeting, ACS will send the sponsor's final unredacted background package to the committee members by overnight mail and to the CDER review division(s).

8. By COB 19 business days prior to the advisory committee meeting, the CDER review division should submit its background package to ACS.

9. By COB 18 business days prior to the advisory committee meeting, ACS will send the CDER background package to the FOI staff for redaction review.

   By COB 18 business days prior to the advisory committee meeting, ACS will send the complete (i.e., unredacted) CDER background package to the committee members by overnight mail.

10. By COB 15 business days prior to the advisory committee meeting, the FOI staff will submit to ACS a redacted version (if any) of the CDER background package.

11. By COB 14 business days prior to the advisory committee meeting, ACS will send to the sponsor by overnight mail a copy of the redacted version of the CDER background package.

12. By COB 8 business days prior to the advisory committee meeting, final discussions with the sponsor on redaction of exempt materials from the CDER package will be completed.

13. By COB 7 business days prior to the advisory committee meeting, CDER will fax and send by overnight mail a letter stating CDER's final decision on redaction of material from the CDER package.

14. By COB 7 business days prior to the advisory committee meeting, the final redacted sponsor package and CDER's redacted package will be submitted by ACS to the Dockets Management Branch for preparation for posting on the FDA website

15. 1 business day prior to the advisory committee meeting (24 hours prior to meeting), FDA will post on its website the sponsor's redacted package and CDER's redacted package. If FDA is unable to post the packages on its website prior to the meeting, the two packages will be made publicly available at the location of the advisory committee meeting, and the two packages will be posted on the Agency website after the meeting. Sponsors are encouraged to bring to the meeting, for public distribution, a reasonable number of hard copies of the slides they will be presenting.

C. Sponsor Submissions That Contain Material Designated by the Sponsor as Exempt From Disclosure (Effect on the Review Clock if Marketing Application is Under Priority Review)

When the product being discussed at an advisory committee meeting covered by this guidance is a product that is the subject of a marketing application that is under priority review by CDER, the process for handling a sponsor package that the sponsor asserts contains materials to be redacted will be handled within the same time frames and expectations described in Section B of this guidance. However, such a submission will be considered an agreement by the sponsor to extend by 2 months the review time for the review cycle in which the advisory committee meeting will be held.