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Joan Kenney
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May 17, 2001

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

Re: Docket No. 01D-0086; Draft Guidance, *Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to Testing or Approval of Biological Products & Convened by Center for Biologics Evaluation and Research,* 66 Federal Register 01-06937 (March 21, 2001)

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2000 alone, Bristol-Myers Squibb dedicated more than $1.8 billion for pharmaceutical research and development activities. The company's more than 4,300 scientists are committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises more than 50 compounds under active development. For these reasons, we are very interested in and well qualified to comment on the Center for Biologics Evaluation and Research's (CBER) draft guidance regarding disclosure of information to Advisory Committees.

Bristol-Myers Squibb commends CBER on producing a guidance that begins to mirror that of the Center for Drug Evaluation and Research (CDER). However, in light of harmonization between the Centers, there are several aspects of this draft guidance for which we welcome the opportunity to comment.

Summary of BMS Comments on Proposal

It is important that the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) harmonize guidances and procedures in order to ensure consistency in the application of the legal agreement between the FDA and Public Citizen. There are several aspects of the proposed guidance that appear contrary to what has already been stated by CDER in their guidance entitled "Disclosing Information Provided to

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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" effective January 1, 2000. Bristol-Myers Squibb would like to take this opportunity to comment on the differences between CDER and CBER's guidance and the potential for confusion that this may cause.

Specific Comments (Items that Need Clarification & Recommended Actions)

Section III. Applicability of Disclosure Procedures Described in the Guidance

Both CDER and CBER guidances address applicability of disclosure procedures for BLAs, NDAs, BLA & NDA supplements, PMAs, and ANDAs. However, the CDER guidance is in direct conflict with procedures pertaining to the BLA/BLA supplement when there is a segregable portion of the CDER advisory committee meeting where a BLA will be presented. At such time, CDER states that the "BLA or PMA will not be subject to the disclosure procedures described in this guidance." The CBER guidance states that the BLA/BLA supplement will be subject to disclosure for all open advisory committee meetings convened by CDER. CBER is specific in addressing the non-applicability of PMAs before a CBER advisory committee meeting. CDER is silent on PMAs with the exception that both CBER and CDER agree that a PMA discussed in unison with an NDA/BLA is subject to disclosure procedures. It is clear that some of this conflict is a result of the issuance of these two guidances at different time frames due to the FDA decision that the Public Citizen's legal settlement concerning CDER advisory committee meetings would also apply to CBER. In the interest of harmony and consistency, applicability of disclosure procedures should be the same for both guidances.

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

CBER and CDER differ substantially in regard to trade secret and confidential commercial information. The CBER guidance does not specifically mention "unpublished reports" in its list of items considered to be trade secret or confidential commercial. However, CDER's guidance includes "unpublished reports" as items considered to be trade secret. It would be helpful to all interested parties if there was agreement on this issue between the two Centers. CBER goes one step further in elucidating materials considered to be trade secret or confidential commercial by providing a helpful definition of raw data and summaries. This definition should be incorporated into both guidances.

Section V. Timing of Sponsor's Advisory Committee Submissions and CBER Review

The CBER and CDER guidances both provide specific timelines for submission of materials to the Scientific Advisors and Consultants Staff (SACS) or Advisors and Consultants Staff (ACS). These timelines are delineated according to whether the sponsor's materials submitted to SACS / ACS are fully redacted or require further redaction by FDA. The CDER and CBER guidances

both rely on the following headings in their guidance to make this distinction:

A. Fully Releasable Sponsor Submissions
B. Sponsor Submissions that Contain Materials Designated by the Sponsor as Exempt from Disclosure

Unfortunately, the time frames for submission under each of these headings are substantially different between the two Centers. It should be noted that in today's pharmaceutical industry, the same individuals filing an NDA may also be responsible for filing a BLA. Thus, it is conceivable that one could inadvertently rely on the wrong guidance in preparing for an advisory committee meeting. Essential timelines for submission of materials in preparation for a public advisory committee meeting should be harmonized. A chart delineating the differences in time frames, as well as the similarities, between CBER and CDER is appended to assist you in your review. Such differences add little to the public disclosure process except to add unnecessary confusion. We would ask that every consideration be given to eliminate these differences.

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

When a sponsor asserts that their priority review package contains materials to be redacted, the CBER guidance does not clearly define the effect that the redaction will have on the review clock. The CBER guidance only states that redaction may mean that the application might "miss the Prescription Drug User Fee Act (PDUFA) performance goal of acting on the priority applications within 6 months of receipt." However, the CDER guidance clearly states failure to provide a completed redacted submission would automatically extend the review clock by a period of two months. In the interest of consistency, both Centers should define the expected time frame for delay of the PDUFA user fee date when a priority review product requires advisory committee materials to be redacted. Thus, we recommend that the two month time frame should be applicable to both Centers in this instance.

BMS appreciates the opportunity to provide comment and respectfully requests that the FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested. In the spirit of harmonization, we suggest that you consider combining the two guidances and issue a joint CBER/CDER disclosure guidance.

Sincerely,

Laurie Smaldone /J.M. Keaney

Laurie Smaldone
Senior Vice President
Regulatory Science and Outcomes Division

Enclosure (1)

Comparison of CDER and CBER Draft Guidance Regarding Disclosure of Information to Advisory Committees

Item	CDER	CBER
A. Fully Releasable Sponsor Submissions	*DAYS PRIOR TO MEETING*	*DAYS PRIOR TO MEETING*
1. Sponsor submits background package to Agency Advisors and Consultants Staff (ACS or SACS)	22	19
2. Sponsor package sent out to committee members, et al.	21	18
3. Agency review divisions submit background package to advisors (ACS or SACS)	19	19
4. ACS or SACS sends Agency complete background package to FOI staff for redaction review	18	18
5. Unredacted Agency background package sent to committee members	18	18
6. FOI staff sends ACS or SACS redacted version of Agency background package	15	15
7. ACS or SACS sends sponsor redacted version of Agency background	14	14
8. Final discussions w/sponsor on redaction of exempt materials from Agency package completed	8	9
9. Sponsor receives final decision on redaction of material from Agency package	7	7
10. Sponsor and redacted Agency packages sent to Dockets Management Branch for preparation for web posting	7	7
11. Sponsor and Agency packages posted on Web	1 day (24 hours)	1 day (24 hours)
B. Sponsor Submissions Containing Material Exempt from Disclosure	*DAYS PRIOR TO MEETING*	*DAYS PRIOR TO MEETING*
1. Complete and redacted versions of sponsor background package submitted to ACS or SACS	48	45
2. ACS or SACS to send one copy of sponsor submission to FOI staff and review division	47	44
3. Agency sends letter to sponsor regarding materials it feels should be redacted from sponsor package.	35	32
4. Final discussions w/sponsor regarding redacted materials in sponsor package completed	30	27
5. Final position on redaction of materials sent to sponsor	28	25
6. Sponsor's complete and redacted final package submitted to ACS or SACS	22	19
7. Sponsor's final unredacted background package sent to committee members by ACS or SACS	21	18
8. Agency review division submits background package to ACS or SACS	19	19
9. Agency background package sent to FOI staff for redaction review by ACS or SACS	18	18
10. Unredacted Agency background package sent to committee members by ACS or SACS	18	18
11. Redacted version of Agency background package submitted to ACS or SACS by FOI staff	15	15

Comparison of CDER and CBER Draft Guidance
Regarding Disclosure of Information to Advisory Committees

12. Redacted version of Agency background package sent to sponsor by ACS or SACS	14	14
13. Final discussions with sponsor regarding redacted materials from Agency package completed	8	9
14. Final decision regarding redaction of material sent to sponsor	7	7
15. Sponsor and redacted Agency packages sent to Dockets Management Branch for preparation for web posting	7	7
16. Sponsor and Agency packages posted on Web	1 day (24 hours)	1 day (24 hours)