



Corporate Regulatory and Quality Science

7052 10 JUL -7 2004

April Veoukas
Corporate Regulatory Affairs
D-3QC, AP6C-1
Telephone: (847) 937-8197

100 Abbott Park Road
Abbott Park, Illinois 60064-6091
Facsimile: (847) 938-3106
E-mail: april.veoukas@abbott.com

July 2, 2004

Division of Dockets Management (HFA -305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: Combination Products, Timeliness of Premarket Reviews, Dispute Resolution; Draft Guidance [Docket 2004D-0182]

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA's draft guidance, "Combination Products, Timeliness of Premarket Reviews, Dispute Resolution," published in the Federal Register on May 4, 2004 at 69 FR 24653.

Thank you for the opportunity to provide these comments. The Office of Combination Products (OCP) serves a valuable function in facilitating the review of combination products. To maximize OCP's effectiveness and the usefulness of this guidance document we recommend clarification of specific review provisions and that the guidance document address OCP's role in qualitative areas of the review process, which impact the timeliness of submission review. These points are discussed below.

On page two under Section III "What are the applicable time frames?" the guidance document states "[w]hen a combination product is to be reviewed under one premarket application...the performance goals associated with that type of application would apply." For purposes of clarity, we recommend the document clearly state the consulting center will provide its review to the lead center within the lead center's required statutory review deadline, even if the lead center's timeframes are more aggressive (shorter) than the consulting center's submission statutory timeframes.

Section III also states on page two "[w]hen a combination product is reviewed under two premarket applications, FDA believes that the performance goals associated with both types of premarket applications would apply." This approach is troublesome, as it leaves the applicant with no recourse when the first constituent part is approved by the center with a more aggressive statutory review timeframe. Because it is necessary to receive approval of both constituent parts, for combination products requiring two applications, the applicant must await the review of the second constituent part to market the product.

2004D-0182

C 1



By default the applicant is subject to the center with the longer review timeframe. As the coordinated approval of both applications is essential for a combination product, an applicant should be able to raise a timeliness dispute as soon as one constituent part is approved, so approval of the second constituent part occurs in a timely manner. Further, for combination products involving two applications, OCP should designate a lead center that would be the center of first contact to resolve timeframe issues involving either center. If the lead center does not provide the applicant with a satisfactory response, it would be appropriate to direct the timeliness dispute to OCP.

In addition to resolving disputes pertaining to the statutory submission review times, OCP can play a role in facilitating the qualitative aspects of combination product reviews, which impact submission review timeliness. Specifically, we recommend OCP's dispute resolution guidance document address the ability of an applicant to access OCP to resolve disputes pertaining to qualitative aspects of product review such as pre-submission meetings/consultations, communication with the sponsor during the review process, and articulation of questions that arise during the review, as these factors impact the timeliness of submission review.

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

A handwritten signature in cursive script that reads 'April Veoukas'.

April Veoukas, J.D.
Associate Director, Regulatory Affairs
Corporate Regulatory and Quality Science
Abbott Laboratories



Corporate Regulatory and Quality Science

April Veoukas
Corporate Regulatory Affairs
D-3QC, AP6C-1
Telephone: (847) 937-8197

100 Abbott Park Road
Abbott Park, Illinois 60064-6091
Facsimile: (847) 938-3106
E-mail: april.veoukas@abbott.com

July 2, 2004

Division of Dockets Management (HFA –305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: Combination Products, Timeliness of Premarket Reviews, Dispute Resolution; Draft Guidance [*Docket 2004D-0182*]

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA's draft guidance, "Combination Products, Timeliness of Premarket Reviews, Dispute Resolution," published in the Federal Register on May 4, 2004 at 69 FR 24653.

Thank you for the opportunity to provide these comments. The Office of Combination Products (OCP) serves a valuable function in facilitating the review of combination products. To maximize OCP's effectiveness and the usefulness of this guidance document we recommend clarification of specific review provisions and that the guidance document address OCP's role in qualitative areas of the review process, which impact the timeliness of submission review. These points are discussed below.

On page two under Section III "What are the applicable time frames?" the guidance document states "[w]hen a combination product is to be reviewed under one premarket application...the performance goals associated with that type of application would apply." For purposes of clarity, we recommend the document clearly state the consulting center will provide its review to the lead center within the lead center's required statutory review deadline, even if the lead center's timeframes are more aggressive (shorter) than the consulting center's submission statutory timeframes.

Section III also states on page two "[w]hen a combination product is reviewed under two premarket applications, FDA believes that the performance goals associated with both types of premarket applications would apply." This approach is troublesome, as it leaves the applicant with no recourse when the first constituent part is approved by the center with a more aggressive statutory review timeframe. Because it is necessary to receive approval of both constituent parts, for combination products requiring two applications, the applicant must await the review of the second constituent part to market the product.



By default the applicant is subject to the center with the longer review timeframe. As the coordinated approval of both applications is essential for a combination product, an applicant should be able to raise a timeliness dispute as soon as one constituent part is approved, so approval of the second constituent part occurs in a timely manner. Further, for combination products involving two applications, OCP should designate a lead center that would be the center of first contact to resolve timeframe issues involving either center. If the lead center does not provide the applicant with a satisfactory response, it would be appropriate to direct the timeliness dispute to OCP.

In addition to resolving disputes pertaining to the statutory submission review times, OCP can play a role in facilitating the qualitative aspects of combination product reviews, which impact submission review timeliness. Specifically, we recommend OCP's dispute resolution guidance document address the ability of an applicant to access OCP to resolve disputes pertaining to qualitative aspects of product review such as pre-submission meetings/consultations, communication with the sponsor during the review process, and articulation of questions that arise during the review, as these factors impact the timeliness of submission review.

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

A handwritten signature in cursive script that reads 'April Veoukas'.

April Veoukas, J.D.
Associate Director, Regulatory Affairs
Corporate Regulatory and Quality Science
Abbott Laboratories