DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 9-23-04 @ 3.
Publication Date 9-28-04
DDM
Certifier R. LEDESMA

[Docket No. 2004D–0410]

Draft Guidance for Industry and Food and Drug Administration Staff: Application User Fees for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry and FDA Staff: Application User Fees for Combination Products." This draft guidance provides guidance to industry and FDA staff on marketing application user fees for combination products. The guidance also describes how the "barrier to innovation" waiver provision under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (act) may be applied to innovative combination products in the infrequent situation where FDA requires the submission of two marketing applications.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that

office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

A combination product is a product comprised of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device and a biological product. Depending upon the type of combination product, approval, clearance or licensure may be obtained through submission of a single marketing application, or through separate marketing applications for the individual constituent parts of the combination product. For most combination products, a single marketing application is sufficient for the product's approval, clearance, or licensure. In some cases, two marketing applications may be submitted for a combination product when one application would suffice. For example, a sponsor may choose to submit two applications when one would suffice in order to receive some benefit from having two applications. In other cases, FDA may determine that two marketing applications are necessary.

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce certain

human drug and biological products. The Medical Device User Fee and Modernization Act of 2002 amended the act to provide for user fees for the review of device applications. When a company requests approval of a new drug, device or biological product prior to marketing, it must submit an application along with a fee to support the review process.

This document provides guidance to industry and FDA staff on marketing application user fees for combination products as defined under 21 CFR 3.2(e). The guidance document explains that combination products for which a single marketing application is submitted will be assessed the user fee associated with that particular type of marketing application. The document explains that, if a sponsor chooses to submit two marketing applications when one would suffice, a user fee for each application would ordinarily be assessed. The document also explains that, in the infrequent situation where FDA requires two marketing applications for a combination product, two application fees would ordinarily be assessed. However, the guidance also describes how the PDUFA "barrier to innovation" waiver provision may be applied to innovative combination products for which FDA requires the submission of two marketing applications. Such a waiver would provide a reduction in application user fees equivalent to the additional fee burden associated with the submission of two marketing applications. This guidance does not address how FDA will determine whether a single marketing application or multiple marketing applications should be submitted for a combination product. Such guidance is in development and will be provided separately for public review and comment.

II. Significance of Guidance

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on application user fees for combination products. 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.

III. Electronic Access

To receive "Guidance for Industry and FDA Staff: Application User Fees for Combination Products," you may either send a fax request to 301–427–1935, or an e-mail request to *combination@fda.gov* to receive a hard copy or electronic copy of the document.

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/oc.combination/default.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

IV. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are

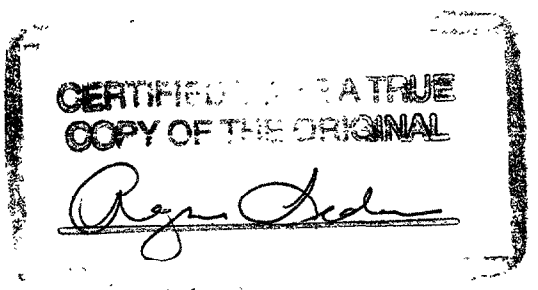
available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/22/04
September 22, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date _____
Publication Date _____
Certifier R. VEDESMA

[Docket No. 2004D–0410]

Draft Guidance for Industry and Food and Drug Administration Staff: Application User Fees for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry and FDA Staff: Application User Fees for Combination Products." This draft guidance provides guidance to industry and FDA staff on marketing application user fees for combination products. The guidance also describes how the "barrier to innovation" waiver provision under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (act) may be applied to innovative combination products in the infrequent situation where FDA requires the submission of two marketing applications.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that

office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

A combination product is a product comprised of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device and a biological product. Depending upon the type of combination product, approval, clearance or licensure may be obtained through submission of a single marketing application, or through separate marketing applications for the individual constituent parts of the combination product. For most combination products, a single marketing application is sufficient for the product's approval, clearance, or licensure. In some cases, two marketing applications may be submitted for a combination product when one application would suffice. For example, a sponsor may choose to submit two applications when one would suffice in order to receive some benefit from having two applications. In other cases, FDA may determine that two marketing applications are necessary.

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce certain

human drug and biological products. The Medical Device User Fee and Modernization Act of 2002 amended the act to provide for user fees for the review of device applications. When a company requests approval of a new drug, device or biological product prior to marketing, it must submit an application along with a fee to support the review process.

This document provides guidance to industry and FDA staff on marketing application user fees for combination products as defined under 21 CFR 3.2(e). The guidance document explains that combination products for which a single marketing application is submitted will be assessed the user fee associated with that particular type of marketing application. The document explains that, if a sponsor chooses to submit two marketing applications when one would suffice, a user fee for each application would ordinarily be assessed. The document also explains that, in the infrequent situation where FDA requires two marketing applications for a combination product, two application fees would ordinarily be assessed. However, the guidance also describes how the PDUFA "barrier to innovation" waiver provision may be applied to innovative combination products for which FDA requires the submission of two marketing applications. Such a waiver would provide a reduction in application user fees equivalent to the additional fee burden associated with the submission of two marketing applications. This guidance does not address how FDA will determine whether a single marketing application or multiple marketing applications should be submitted for a combination product. Such guidance is in development and will be provided separately for public review and comment.

II. Significance of Guidance

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on application user fees for combination products. 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.

III. Electronic Access

To receive "Guidance for Industry and FDA Staff: Application User Fees for Combination Products," you may either send a fax request to 301–427–1935, or an e-mail request to *combination@fda.gov* to receive a hard copy or electronic copy of the document.

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/oc.combination/default.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are

available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/22/04
September 22, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S