DRAFT

ATTACHMENT G
July 16, 1993

INTERIM GUIDANCE DOCUMENT FOR WAIVERS OF AND REDUCTIONS IN USER FEES

I. Introduction

On October 29, 1992, the Prescription Drug User Fee Act of 1992 (the User Fee Act or the Act), Public Law 102-571, was signed. It requires the Food and Drug Administration (FDA) to assess and collect user fees for certain applications, products, and establishments.

The revenues generated from user fees will be dedicated to expediting the drug and biologic review processes in accordance with specific performance goals described in the House Report (H.R. Rep. No. 102-895, 102d Cong., 2d Sess., at 17 (1992) (House Report)) and referenced in the User Fee Act. These fees are expected to fund over 600 additional positions for review staff in FDA's Center for Drug Evaluation and Research (CDER) and in its Center for Biologics Evaluation and Research (CBER), and other support staff, to be recruited over the next five years. These additional staff will be used to accelerate review of human drug applications, and for activities associated with the Act's implementation. This expedited review should ultimately result in products reaching the market faster, thereby providing benefits to the public in the form of earlier access to certain

FDA-approved therapies. Reduced review time and approval of such therapies should also provide financial benefits to drug and biologic manufacturers in the form of earlier marketing of approved products which should result in earlier access to revenues which could well total millions of dollars per product.

The User Fee Act permits FDA to grant certain waivers and reductions from user fees under limited circumstances. 21 U.S.C. § 379h(d). In the House Report accompanying the legislation, Congress anticipated that FDA would identify, through informal guidelines, the circumstances under which potential user fees might be waived or reduced (House Report at 17). This interim guidance document describes the various fee provisions (section II), the data that FDA expects to review and consider in evaluating requests for fee waivers or reductions (section III), the procedures that FDA suggests be used to request fee waivers or reductions (section IV), and the contact point for this interim guidance document (section V).

This interim guidance document does not bind the agency, nor does it create or confer any rights, privileges, or benefits for or on any person[1]. It does, however, describe FDA's present intentions regarding implementation of the fee waiver and

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[1] For purposes of this guidance document, the term "person" includes an "individual, partnership, corporation, and association." (House Report at 13) This document will use the term "person" or "entity" when referring to a sponsor or applicant.

reduction provisions of the User Fee Act. Because this guidance document describes the information that FDA expects to consider in deciding whether a person qualifies for a fee waiver or reduction, FDA recommends that a person follow the format and procedures that FDA has outlined in it. The submission of alternative information or the use of an alternative format or procedure, while permissible, may not provide the agency with all of the information necessary for its evaluation of a request for a fee waiver or reduction. Therefore, FDA recommends that persons submit the information identified in this interim guidance document and use the format and procedures described to enable the agency to expedite its evaluation of the request and enhance the likelihood that qualifying persons will promptly receive the benefits of a fee waiver or reduction.

FDA will evaluate its experience in working with this guidance document, may revise this document periodically, and may ultimately propose regulations for this process.

FDA's decision to grant a fee waiver or reduction will be based on the statutory standards for waivers and reductions taking into account the underlying purpose of the User Fee Act and the impact of overall waivers and reductions on the fee revenue schedule set forth in the Act. 21 U.S.C. § 379h(b)(1). In implementing the fee waiver and reduction provisions, FDA will consider Congress' intent to benefit the public health by accelerating the review

and approval of certain prescription drug and biologic products through user fees, making such products available more quickly to those needing treatment. To accomplish this goal, an adequate and stable financial base is necessary to enable FDA to obtain and maintain the resources required to sustain a reduced review time.

Because the User Fee Act requires FDA to recalculate fee schedules each year to achieve the total fee revenues set forth in that statute, a high number of waivers and reductions could have the effect of raising overall fees for applications, products, and establishments in subsequent years. 21 U.S.C. §§ 379h(b) and (c). The resulting higher fees could deter the submission of applications for new products and, thus, have an adverse impact on public health. Ordinarily, FDA expects to grant a reduction or waiver of an establishment or product fee only for the current year for the reasons discussed above. If a person wishes to have an establishment or product fee waived or reduced in subsequent years, it should make a new request for a waiver or reduction.

A request for a fee waiver or reduction under the User Fee Act must be distinguished from assertions that certain types of fees are not applicable to an application, product, or establishment. FDA will assess and collect the fees as required by the User Fee Act. 21 U.S.C. § 379h(a). If an application, product, or

establishment meets the statutory criteria, a fee is due unless a person qualifies for a fee waiver or reduction, applies for such a waiver or reduction, and the waiver or reduction is granted. If, however, an application, product, or establishment does not meet the statutory criteria for imposition of a fee because it meets one or more exclusions, then no application for a waiver or reduction is necessary. For example, generic drug applications submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(j), and applications for certain biological products such as allergenic extract products and whole blood or blood components for transfusion are, by definition, not subject to fees because such applications are expressly excluded from the definition of a "human drug application." 21 U.S.C. § 379g(1). No waivers need to be requested for these products. 21 U.S.C. § 379g(1).

The User Fee Act provides that a human drug application or supplement submitted by a person subject to application or supplement fees "shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid." 21 U.S.C. § 379h(e). FDA will expect that all fees due and payable at the time of the submission should be paid without regard to any pending request for a fee waiver or reduction. This approach will help ensure that the steady funding stream Congress intended will be achieved and should minimize the filing of unmeritorious waiver requests. If,

after filing, FDA determines that a person qualifies for a fee waiver or reduction, the agency will issue a refund.

The only provision in the Act permitting a deferral of the entire payment of any fee is the small business exception, under which entities qualifying for that exception are not required to pay any part of the application fee prior to the application's submission. In that case only, the fee due need not be paid until one year after the submission of the application. 21 U.S.C. § 379h(b)(2); 21 U.S.C. §§ 379h(a)(1)(B), (2) and (3). Otherwise, deferral of fees based on waiver or reduction requests is not provided for in the Act and, as discussed above, would result in an unstable fee base, and might encourage the submission of frivolous waiver or reduction requests.

In the future, to avoid having to pay the fee and then wait for a refund, persons are encouraged to submit requests for fee waivers or reductions 90 days before required fees are expected to be paid. For application or supplement fees, this would be 90 days before the expected submission of the application or supplement. For product and establishment fees, this would be by November 1 of each fiscal year because it is expected that annual product and establishment fees will be paid by January 31 of each year.

FDA recognizes that the factors that support fee waiver or reduction requests may change. Therefore, to ensure that a fee

waiver or reduction request is based upon current information, persons are requested to time their fee waiver or reduction requests carefully. Normally, the fee waiver or reduction request should not be submitted more than 90 days in advance of the date payment will be due. If a waiver or reduction is granted in advance of the payment date, when the fee is due, the person should certify that conditions or circumstances described in the initial request remain unchanged.

II. Types of Fees

A. Application Fees

The User Fee Act requires FDA to collect an application fee from each person who submits certain human drug applications or supplements[2] on or after September 1, 1992. 21 U.S.C. § 379h(a)(1). Human drug applications or supplements covered by fees are those submitted on or after September 1, 1992, under sections 505(b)(1) of the FD&C Act, 21 U.S.C. § 355(b)(1), and those submitted after September 30, 1992, under section 505(b)(2) of the FD&C Act, 21 U.S.C. § 355(b)(2), which request approval of a new active ingredient or new indication for a use not

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[2] Changes to approved biological product license applications (PLA's) are called "amendments." Changes to unapproved new drug applications (NDA's) are also called "amendments" but changes to approved new drug applications are called "supplements." To avoid confusion, in this document the term "amendment" will be used to refer to changes to NDA's, PLA's, and biological establishment license applications (ELA's) submitted before an application is approved, and "supplement" will refer to changes to NDA's, PLA's, and ELA's submitted after approval. CBER intends to incorporate this terminology into its regulations.

previously approved under an application submitted pursuant to section 505(b) of the FD&C Act, 21 U.S.C. § 355(b); applications for initial certification or initial approval of an antibiotic drug under section 507 of the FD&C Act, 21 U.S.C. § 357; or an application for licensure of a biological product under section 351 of the Public Health Service Act (PHSA), 42 U.S.C. § 262.

Applications and supplements specifically excluded from fees under the User Fee Act include those for: generic drug products submitted pursuant to section 505(j) of the FD&C Act, 21 U.S.C. § 355(j); whole blood or blood components for transfusion; supplements for bovine blood products for topical application licensed before September 1, 1992; allergenic extract products; in vitro diagnostic biologic products licensed under section 351 of the PHSA, 42 U.S.C. § 262; and supplements for large volume parenteral (LVP) drug products approved before September 1, 1992. 21 U.S.C. § 379g(1).

For Fiscal Year (FY) 1993, the fees for original applications submitted with clinical data are $100,000 per application; the fees for original applications without clinical data, and supplements with clinical data, are $50,000 per application or supplement. 21 U.S.C. § 379h(b). Except for entities qualifying for the small business exception (see section III (A)), one-half of the application fee must be paid at the time the application or supplement is submitted. The remainder of the

fee must be paid within 30 days of the date that an FDA action letter on that application is received by the person, or upon withdrawal of the application or supplement. 21 U.S.C. § 379h(a)(1)(B).

B. Establishment Fees

The User Fee Act requires FDA to collect an annual establishment fee from each person that 1) owns a prescription drug establishment at which is manufactured at least one prescription drug product within the meaning of the User Fee Act, 21 U.S.C. § 379g(3), which is not the same as a product approved under section 505(b)(2) or 505(j) of the FD&C Act; and 2) after September 1, 1992, had pending before the Secretary a human drug application or supplement. 21 U.S.C. § 379h(a)(2). The establishment fee will be payable within 30 days of the date invoices are sent in 1993, and on or before January 31 of subsequent years. The fees for each establishment are $60,000 in FY 1993. 21 U.S.C. § 379h(a)(2) and § 379h(b)(1).

A prescription drug establishment is defined in the User Fee Act as follows: 1) a foreign or domestic place of business; 2) at one general physical location consisting of one or more buildings all of which are within 5 miles of each other; 3) which manufactures finished dosage forms at such location; and 4) is under the management of a person listed as the applicant in a human drug application for a prescription drug product with

respect to one such product.[3] Facilities whose sole function is packaging are not subject to establishment fees. 21 U.S.C. § 379g(5).

C. Product Fees

The third type of fee is an annual product fee for each prescription drug product listed under section 510 of the FD&C Act, 21 U.S.C. § 360, that is not the same as a product approved under sections 505(b)(2) or 505(j) of the FD&C Act. Whole blood or blood components for transfusion, bovine blood products for topical application licensed before September 1, 1992, allergenic extract products, in vitro diagnostic biologic products licensed under section 351 of the PHSA, 42 U.S.C. § 262, and large volume parenteral drug products approved before September 1, 1992 are excluded from product fees. The fees will be collected from each person named as the applicant in a human drug application for a listed drug product who, after September 1, 1992, had pending a human drug application or supplement. 21 U.S.C. § 379h(a)(3). The fee is payable at the time of the first such listing of that product in each calendar year and is payable only once each year for each product regardless of how many times the

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[3] "Establishment" is defined differently under the User Fee Act than it is for licensing under the Public Health Service Act. Under the User Fee Act, each separate establishment, as defined in that statute, outside of a five mile radius, is subject to a separate fee notwithstanding that such establishments may be the subject of one establishment license under the PHSA.

product is listed. 21 U.S.C. § 379h(a)(3). The product fee for FY 1993 is $6,000 per listed product. 21 U.S.C. § 379h(b).

III. Fee Exceptions, Waivers and Reductions

A. Small Business Exception to the Application Fee

The User Fee Act provides for a reduction and deferral of the application fee for any business which has fewer than 500 employees, including employees of affiliates, and which does not have a prescription drug product introduced or delivered for introduction into interstate commerce. 21 U.S.C. § 379h(b)(2). The User Fee Act defines an "affiliate" as one business with direct or indirect control of another, or one business with the power to control the other, or a third party that controls or has the power to control both businesses. 21 U.S.C. § 379h(b)(2). Under this statutory exception, a qualifying small business need pay only one-half the amount of the fee for an original human drug application it submits.[4] No fee is due until one year after the date of submission[5] of such application. FDA will send an invoice for the fee one year after the application was submitted. The first installment of the fee will be due at that time, whether or not an action letter has been issued; the second

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[4] The Act does not provide for a small business exception for supplements.

[5] "Date of Submission" is the date the application is received by the FDA and stamped as received in the CDER Central Document Room or the CBER Document Control Center. This should be distinguished from "filing" of the application, which occurs after FDA has determined that the application is sufficiently complete to permit a substantive review. 21 CFR § 314.101.

installment will be due at the same time if an action letter has already been issued.

The number of employees is to be calculated in accordance with the procedures and regulations of the Small Business Administration (SBA) (House Report, p. 17) (13 C.F.R. Part 121 (1993)). The suggested procedures for requesting this exception are contained in sections IV (A) and (B) of this document.

B. Fee Waiver or Reduction (Section 736(d), 21 U.S.C. § 379h(d))

The statute provides:

> the Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) [application, product, or establishment fees] where the Secretary finds that --
> (1) such waiver or reduction is necessary to protect the public health,
> (2) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,
> (3) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or
> (4) assessment of the fee for an application or a supplement filed under section 505(b)(1) pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 505(b)(2) could not be assessed fees under subsection (a)(1) [section 736(a)(1) of the User Fee Act].

Each of these statutory sections is discussed in turn below.

1. Necessary to Protect Public Health or Significant Barrier to Innovation (First and Second Statutory Grounds for Waiver or Reduction)

FDA will consider a waiver or reduction of application, product, or establishment fees, from persons subject to those fees who request such a waiver or reduction and who demonstrate that a waiver or reduction is necessary to protect the public health or to prevent a significant barrier to innovation.

The legislative history (House Report at 17) indicates that Congress granted waiver authority to FDA to alleviate the burden of fees where such fees are a barrier to an entity's ability to bring, or to continue to bring to market products that are innovative or that promote the public health. The legislative history notes that FDA may waive or reduce fees unless such a waiver or reduction is not necessary to protect the public health, or it is apparent that the fee will not be a disincentive to innovation. The House Report expressly notes that FDA should consider the "limited resources" of the entity when evaluating a request for a fee waiver or reduction. Id.; see also 138 Cong. Rec. S17,239 (daily ed. Oct. 7, 1992)(joint statement of Sen. Kennedy and Sen. Hatch).

FDA has interpreted the public health and innovation fee waiver or reduction provisions in light of this legislative intent, to provide relief from user fees if such fees are a barrier to an entity's ability to develop or market specific products or to

otherwise continue to pursue innovative technology. Of the three applicable fees, FDA believes that the annual establishment fee has the greatest potential to burden small entities and to become a barrier to public health and innovation for such entities. Therefore, FDA expects that most of the fee waivers or reductions granted under the public health and innovation sections of the User Fee Act will be to small entities where annual establishment fees would be disproportionate in relation to their revenues.

FDA realizes that an excessive number of requests for fee waivers or reductions from persons who ultimately are unable to demonstrate that the fees are a barrier to innovation or to the development and marketing of products that benefit the public health would have a detrimental impact on the agency's ability to implement the User Fee Act. FDA has considered its resources available to evaluate requests for waivers or reductions, and recognizes that its ability to promptly review such requests will affect its ability to provide timely relief for those persons truly unable to meet the financial requirements of the User Fee Act. Furthermore, FDA recognizes that if it grants an excessive number of fee waivers or reductions, in successive years the overall fees for other persons must be increased to ensure that FDA obtains the annual total fee revenues specified in the User Fee Act. Thus, FDA is describing here its general approach to determining eligibility for fee waivers or reductions under the public health and innovation sections to encourage only those

persons likely to qualify for fee waivers and reductions to submit requests, and to discourage requests by persons that would not easily establish that the fee is a barrier to their ability to market and develop products that benefit the public health or are innovative.

FDA expects to evaluate a person's or entity's request for a fee waiver or reduction under the public health or innovation sections based on the annual revenues of the entity and its affiliates (both domestic and foreign revenues will be evaluated). FDA will accept a certified statement from the entity with respect to this information. (See section IV(C)). Any confidential commercial or financial information that FDA obtains through this process will be maintained in accordance with the provisions of the Freedom of Information Act, 5 U.S.C. § 552, and FDA's regulations implementing that Act, 21 C.F.R. Part 20.

In evaluating whether the fees are a barrier to public health and innovation, the agency expects to consider the relationship between the annualized cost of user fees and the gross annual revenues of the entity, or of that entity's parent company or other major funding sources (if it is 50 percent or more owned by, or derives significant funding from, other entities), or of its total operating budget if it is a "not-for-profit" organization. Since even very large entities may show operating

losses, FDA does not intend to consider lack of profitability as evidence of limited resources.

In general, FDA expects entities to fall into certain groups based on their size and ownership. Pharmaceutical entities range in size from those with revenues less than $1 million annually to those with annual revenues in the billions of dollars. Table 1 is a summary of seven types of entities. FDA expects to use this sort of information to decide whether an entity has demonstrated that it is unable to pay the fee because of limited resources and, therefore, the fee would be a barrier to developing products that would benefit the public health or are innovative.

FDA, generally, does not expect to grant many fee waivers or reductions to large or medium-sized entities whether for-profit or not-for-profit (Types 1, 2, 3, or 7), except in rare and unusual circumstances that are unrelated to the entity's overall profitability. FDA does not expect any Type 1 or 2 entities to be able to demonstrate that a fee is a barrier to bringing to market products that benefit the public health or to innovation. FDA does not expect to grant many waivers or reductions to small entities that are owned or funded by larger corporate parents (e.g., Type 3 entities that are owned 50 percent or more by large corporate parents) because it is unlikely they would be able to demonstrate that the fees are a barrier to products that would benefit the public health or that are innovative. FDA does not

expect not-for-profit organizations with large operating budgets (Type 7) to be able to demonstrate that user fees are a barrier to products that would benefit the public health or that are innovative.

Similarly, because small start-up entities (Type 6) will not yet be subject to product or establishment fees, and will qualify for the small business exception (section III(A)), FDA does not expect many of these entities to be able to demonstrate that the partial or reduced application fee is a barrier either to products that benefit the public health or to innovation.

In general, FDA expects to grant most of the fee waivers and reductions under the public health and innovation provisions to entities such as those described as Type 4 or 5 whose ability to pay fees is limited by the entity's resources. Although there is no express threshold for defining a small entity, FDA generally considers an entity with less than $10 million in annual gross revenues and no corporate parent or funding source with annual gross revenues of $100 million or more (Types 4 and 5) as less likely to be able to continue to provide products that benefit the public health and to develop innovative technology because of user fees. However, the impact of the annualized costs of user fees on Type 4 and 5 entities will have to be evaluated on a case-by-case basis.

On occasion, products such as orphan drugs that are innovative and provide public health benefits may be candidates for application fee waivers or reductions, even when these products are developed by medium-sized entities with annual gross revenues of less than $100 million (e.g., certain Type 3 entities). FDA will consider requests for fee waivers or reductions for such products, but does not expect to grant them often.

2. Fees To Be Paid Will Exceed the Costs (Third Statutory Ground for Waiver or Reduction)

Section 736(d) of the User Fee Act, 21 U.S.C. § 379h(d), provides that FDA may grant a waiver from or reduction in one or more fees where the Secretary finds among other things that, "the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person..." 21 U.S.C. § 379h(d)(3). In conducting this evaluation, the Secretary may use "standard costs." 21 U.S.C. § 379h(d). The agency has begun to define the major elements associated with the review of common applications or supplements for which standard costs will be developed and has hired a contractor to assist in this effort. Until these costs have been developed, FDA will hold any fee waiver or reduction requests submitted under 21

When a person submits a request for a fee waiver or reduction based on the assertion that the costs associated with the process for review of human drug applications will be less than the fees, the entity's total business included in "the process for the review of human drug applications" will be evaluated against the cumulative fees paid (application, establishment, and product). All active Investigational New Drug exemptions (INDs) and applications (NDAs, PLAs, ELAs, supplemental ELAs, supplemental NDAs or PLA amendments) of that person will be evaluated against a standard cost of review based upon the characteristics of the items evaluated.

Section 736(a)(1)(D) of the User Fee Act, 21 U.S.C. § 379h(a)(1)(D), provides that the Secretary shall refund 50 percent of the application fee paid for any application or supplement which is not accepted for filing. That is, 50 percent of the fee due upon submission of the application or supplement shall be refunded. Because 50 percent of the entire fee is due upon submission of the application or supplement, the amount required to be refunded under 21 U.S.C. § 379h(a)(1)(D) is 25 percent of the entire application fee applicable at the time of the application's or supplement's original submission. A person whose application is refused for filing may request a waiver or reduction of the 25 percent of the fee not refunded under this provision, if the retained fee would exceed the costs of the

review conducted on the application before it was refused for filing.

To determine whether a waiver or reduction should be granted, FDA will use the standard cost elements described in this section when they are developed. If FDA determines that the fees paid have exceeded the agency's costs related to reviewing the application, including all activity in support of development of the application, the excess will be refunded. Until these standard costs have been adopted, the agency will hold in abeyance any request for waivers or reductions under this provision, and will refund any monies paid should a fee waiver or reduction eventually be granted under it.

3. Inequity With Applications under Section 505(b)(2) of the FD&C Act (Fourth Statutory Ground for Waiver or Reduction)

Section 736(d)(4) of the User Fee Act, 21 U.S.C. § 379h(d)(4), provides that a person with an application or supplement submitted under section 505(b)(1) of the FD&C Act may request a waiver or reduction of the fee for that application or supplement because assessment of a fee would be inequitable because an application or supplement for a product containing the same active ingredient filed by another person under section 505(b)(2) of the FD&C Act could not be assessed application or supplement fees.

Two categories of applications would qualify for waivers or reductions under this provision: 1) any applications or supplements submitted under section 505(b)(1) of the FD&C Act after September 1, 1992, containing the same active ingredient as an application submitted under section 505(b)(2) of the FD&C Act that was submitted between September 1 and September 30, 1992, (which are, therefore, ineligible for fees); or 2) any applications or supplements submitted under section 505(b)(1) of the FD&C Act after September 1, 1992, containing the same active ingredient as an application submitted under section 505(b)(2) of the FD&C Act after September 30, 1992, that would not be assessed a fee because it is not a new active ingredient or new indication for use, and therefore is not a 505(b)(2) "human drug application" covered by user fees.

C. Waiver or Reduction of Fee After Withdrawal After Filing

Section 736(a)(1)(B)(ii) of the User Fee Act, 21 U.S.C. §379h(a)(1)(B)(ii), states that the second 50 percent payment of the application fee is due upon the expiration of 30 days from the date of an action letter or upon withdrawal of a filed application or supplement "unless the Secretary waives the fee or a portion of the fee because no substantial work was performed on such application or supplement after it was filed." The statute specifies that a waiver or reduction under this provision "shall be solely in the discretion of the Secretary and shall not be reviewable." Id. To determine whether substantial work was

performed, FDA will use data to be obtained by the contractor developing the standard cost estimates discussed above. Until such data is available, FDA will hold waiver or reduction requests under this section in abeyance, and will refund any monies paid should a fee waiver or reduction subsequently be granted under this section.

IV. Procedures for Requesting Fee Waivers and Reductions

This section of the interim guidance document contains the procedures that FDA recommends a person follow to request a fee waiver or reduction. These procedures describe the information that the agency believes it needs from a person to determine whether to grant a request for a fee waiver or reduction. Adherence to these procedures will help to minimize time-consuming efforts by the agency to obtain additional necessary information, and will enable the agency to grant fee waivers or reductions to qualifying persons in a timely manner.

The first section applies to all requests for fee waivers and reductions. Additional procedures for requesting waivers or reductions of specified fees are set forth in subsequent sections, as necessary.

A. Procedures Applicable to All Requests for Waivers or Reductions

1. Requesting a Waiver or Reduction

Requests for fee waivers and reductions will be reviewed and granted or denied by FDA's Chief Mediator and Ombudsman (Waiver Officer). Each waiver or reduction request should be submitted in writing and contain the following information:[6]

a. Name of entity, including company name, and name and telephone number of contact person for the fee waiver or reduction request;

b. Specific fee or fees for which a waiver or reduction is requested including:

(1) **For application or supplement fees**, the NDA, PLA, ELA, or supplement number of the application for which a waiver or reduction is sought, the trade and establishment names of products covered by that application, the date the application or supplement was submitted, and whether the application contained clinical data.

(2) **For product fees**, the name of the product, its applicable National Drug Code (NDC), the NDA or PLA number under which the product was approved, the name of the person named as the holder of the application, the specific strength or potency of

[6]If submitting a fee waiver or reduction request in advance of a submission or in advance of the date fees are due, the entity should provide all information available and update the request as soon as the missing information becomes available.

the product, the dosage form, the invoice number, and the invoice date. A photocopy of FDA's invoice to the person may be submitted to provide this information, as long as the waiver request clearly specifies for which specific product the fee waiver or reduction is requested.

(3) **For establishment fees**, the name and address of the establishment for which the waiver or reduction is requested, the establishment number as listed on the invoice, the invoice number, and the invoice date. A copy of the invoice is acceptable.

c. Date on which payment was made or will be made of the fee for which a waiver or reduction is requested (except when the request pertains to the small business exception for the application fee (see section III(A) of this interim guidance document));

d. Statutory provision under which a waiver or reduction is requested;

e. Information and analyses showing the statutory criteria for the waiver or reduction are met.

Three copies of each request for a fee waiver or reduction should be sent to:

Office of the Chief Mediator and Ombudsman (HF-7)
Food and Drug Administration
5600 Fishers Lane, Room 14-105
Rockville, MD 20857.

The Waiver Officer will send a written acknowledgement of receipt of the waiver or reduction request to the person, noting the date on which the Waiver Officer received the waiver or reduction request and requesting any additional information the Waiver Officer believes will be necessary to evaluate the request.

2. Review of the Request

The Waiver Officer will conduct a review of the waiver or reduction request, consulting with relevant agency officials as appropriate. The Waiver Officer may request additional information from, or a meeting with, the person during the review period. The agency expects to notify the person of the Waiver Officer's decision and the reasons for it within 90 days of the receipt of a waiver or reduction request. Any advance waiver or reduction requests submitted will be required to certify when filing the application that no material changes in the information submitted have occurred. This time period may vary depending on, among other things, the number of fee waiver or reduction requests submitted and the sufficiency of the information provided to support the fee waiver or reduction request. Any request requiring completion of FDA standard cost information may be delayed beyond this 90 day period, until FDA's contractor has completed this study.

3. Request for Reconsideration of a Decision

If the Waiver Officer fully or partially denies a request for a fee waiver or reduction, the person may request reconsideration of that decision. FDA encourages persons to make such requests for reconsideration promptly, and suggests that they be made within 15 days of the receipt of the decision denying the requested fee waiver or reduction. A request for reconsideration should state the person's reasons for believing that the Waiver Officer's decision is in error, and should include any additional information necessary to support the person's position. The Waiver Officer will issue a decision upon reconsideration, setting forth the basis for the decision. A request for reconsideration should be filed with and decided by the Waiver Officer prior to any appeal.

4. Appeal of the Waiver Officer's Decision

If a request is denied again on reconsideration, a person may appeal the denial to the Deputy Commissioner for Management and Systems. The appeal should contain a copy of the Waiver Officer's decision, the Waiver Officer's decision upon reconsideration, and a statement of the person's reasons for believing the Waiver Officer's conclusion is in error. The appeal should contain specific references to information or analyses already submitted to the agency that the person believes support its position. No new information should be presented in the appeal.

Three copies of the appeal should be sent to:

Office of the Deputy Commissioner for Management and Systems
Food and Drug Administration
5600 Fishers Lane, (HF-20)
Rockville, MD 20857.

After review of the information submitted, the Deputy Commissioner will issue a written decision on the person's request which will constitute final agency action on that request.

B. Small Business Exception Requests

1. Requesting the Exception

Because no application fee is due from an entity qualifying under the small business exception at the time an application is submitted (see section III(A), supra), in the future a small business seeking to qualify for this exception is encouraged to submit a request for the exception before it submits its application. An entity who believes it qualifies for the small business exception should request the exception approximately 90 days before the application is to be submitted. This time is needed by FDA to conduct the agency's review of the entity's submission and to notify the entity of the decision. FDA discourages a request any earlier than 90 days prior to the anticipated submission of the application, because the factors that support an entity's request for the small business exception

are subject to change, and FDA is unlikely to assume that those factors will continue to exist for greater than 90 days.

In addition to the information requested in section IV(A)(1) of this document, a request for a small business exception should contain a statement from a responsible officer of the entity or organization that it:

a. has fewer than 500 employees including employees of other affiliated companies;

b. does not have a prescription drug product introduced or delivered for introduction into interstate commerce, and does not expect to introduce a prescription drug product within the next twelve months; and

c. expects to be prepared to submit an application to the agency within 90 days of the request.

2. Review of the Small Business Exception Request

Upon receipt of the small business exception request, the Waiver Officer will review agency records to confirm that the entity has no prescription drug products introduced or delivered for introduction into interstate commerce. If the agency's records indicate that the entity does not meet the small business definition in the User Fee Act because it has a prescription drug product introduced or delivered for introduction into interstate commerce, the Waiver Officer will send a letter to the entity denying the exception request. The entity then may submit the

application and pay the required application fee, or follow the procedures provided in section IV(A)(3) of this interim guidance document for reconsideration and appeal. The application will not be filed pending a request for reconsideration or appeal unless the application fee has been paid. 21 U.S.C. § 379h(e). Should reconsideration or appeal result in the small business exception being granted, any fees paid will be refunded.

If the agency's records confirm that the entity does not have any prescription drug products introduced or delivered for introduction in interstate commerce, the Waiver Officer will send a written acknowledgment to the entity, notifying the entity of the agency's intent to request that the Small Business Administration (SBA) evaluate whether the entity meets the size criteria under the User Fee Act for eligibility for the small business exception. 21 U.S.C. § 379h(b)(2). The formal size determination will be made by SBA in accordance with its regulations. (See 13 CFR § 121.1501 et seq.).

If the SBA determines that the entity meets the statutory size eligibility criteria for the small business exception, the Waiver Officer will send to the entity a written notice that the agency will accept an application without payment of an application fee. A copy of this notice should accompany the submission of the application. The application should be submitted not later than 90 days after the date on which the exception was requested.

Because the factors that support a small business determination may change rapidly, if the application is submitted more than 90 days after the exception was requested, the agency is unlikely to continue to assume that the entity is still small. To ensure that eligibility for a small business exception is based upon current information, the person will be asked to re-institute the exception request process, which will involve requesting another size determination by SBA. Accordingly, the agency encourages entities to time their submission of small business exception requests carefully to eliminate unnecessary delay and repetitive size determinations.

If the SBA determines that an entity is other than small, the Waiver Officer will send to the entity a written denial of the small business exception request. If the entity wishes to appeal SBA's conclusion that the entity is other than small, it should follow SBA's appeal procedures set forth in 13 CFR § 121.1701 et seq. In the meantime, the entity may submit its application to FDA for review if it pays the application fee. FDA will not accept an application pending an SBA appeal unless the application fee is paid. 21 U.S.C. § 379h(e).

3. Confirmation of Eligibility at One-Year

Nine months after the date of the submission of the application, FDA will determine whether the entity continues to meet the

statutory criteria for the small business exception. At that time, FDA will review its records to determine whether the entity has, during the previous twelve months, introduced or delivered for introduction into interstate commerce any prescription drug product. If the entity has not introduced or delivered for introduction into interstate commerce any prescription drug product, FDA will request SBA to conduct a second formal size determination of the entity. The second formal size determination will be made nine months to one year after the date of submission of the application.

If the agency determines that the entity has not introduced or delivered for introduction into interstate commerce any prescription drug product since the application was submitted, and if SBA concludes that the entity continues to meet the statutory size criteria for the small business exception, the agency will send an invoice to the entity for 25 percent of the application fee in effect at the time the application was submitted. FDA intends to send the invoice not later than one year from the date the application was submitted, and payment will be due within 30 days. 21 U.S.C. § 379h(b)(2). Any fee not paid within 30 days of the date after it is due, will be treated as a claim of the United States Government. 21 U.S.C. § 379h(b). If FDA has issued an action letter within the meaning of 21 U.S.C. § 379g(6)(B), with respect to that application in

the intervening one-year period, the invoice will be for the full amount (50% of the fee) owed for applications.

If the Waiver Officer determines that, since the application was submitted, an entity has introduced or delivered for introduction into interstate commerce a prescription drug product, or if SBA concludes that the entity no longer meets the statutory size criteria for the small business exception, the Waiver Officer will send a written denial of the request for the small business exception. When the Waiver Officer denies a request for the small business exception, the entity will be required to pay the full application fee that was in effect at the time the application was submitted. Within ten days of the Waiver Officer's denial, the agency plans to send an invoice to the entity for 50 percent of the application fee in effect at the time the application was submitted or for the full fee if FDA has in the interim year issued an action letter. If no action has yet been taken within the meaning of 21 U.S.C. § 379g(6)(B), that action when taken, or the withdrawal of the application, will render the entity liable for the remainder of the fee. See 21 U.S.C. § 379h(a)(1)(B)(ii). Payment will be due within 30 days. 21 U.S.C. § 379h(h).

C. Requests for Fee Waivers or Reductions Based Upon Public Health and Innovation

In addition to the information requested in section IV(A)(1) of this interim guidance document, a request for a fee waiver or reduction under the public health and innovation sections of the User Fee Act should include a statement (certified by a responsible officer of the entity) which certifies to the following information

(1) such waiver or reduction is necessary to protect the public health and/or the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person;

(2) an estimate of the total fees to be paid by the entity for the year;

(3) entity's annual gross revenues and the annual gross revenues of its corporate parent, if any, and all other funding source(s), if any;

(4) relationship to parent, other affiliates, and other funding sources; and

(5) an analysis which demonstrates the financial burden which user fees will place on the entity specific to the product, application, or establishment under discussion.

D. Fees Paid Will Exceed the Costs

Additional information needed to process waivers and reductions under this provision cannot be determined until the agency obtains the necessary data on standard costs. Until that time, fee waiver or reduction requests submitted under this provision should contain, at least, the information requested in section IV(A)(1) of this interim guidance document.

E. Inequity With Applications Submitted Under Section 505(b)(2) of the FD&C Act

In addition to the information requested under section IV(A)(1) of this interim guidance document, a waiver or reduction request submitted under this provision should indicate, with as much specificity as possible, the product approved under section 505(b)(2) of the FD&C Act, the date such product was approved or introduced into commerce, and the reason for the person's belief that an application fee should not be assessed for the product.

V. Further Information

Questions about waivers or reductions of fees under the User Fee Act or this interim guidance document may be addressed to the

Office of the Chief Mediator and Ombudsman (HF-7)
Food and Drug Administration
5600 Fishers Lane, Room 14-105
Rockville, MD 20857.

The office telephone number is (301)443-1306.

TABLE 1
TYPES OF ENTITIES

TYPE	SIZE[7]	DESCRIPTION
1	Parent Corporation has revenues ≥ $1 Billion	Major Pharmaceutical Firms
2	Parent Corporation has gross annual revenues ≥ $300 Million and < $1 Billion	Mainstream Pharmaceutical Firms with Large or Mid-size World Revenues
3	Parent Corporation has gross annual revenues ≥ $10 Million and < $300 Million	Pharmaceutical Firms with Small or Mid-size World Revenues
4	Parent Corporation has revenues of $1 to $9.99 Million	Small Companies
5	Parent Corporation has revenues < $1 Million	Very Small Companies
6	Less than 500 employees--qualifies for small business exception in Statute	Small Start-Up Companies with First User Fee Application
7	Size Varies	Non-Profit Organizations (Government, Charity, University)

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[7] Revenues calculated include domestic and foreign sales. If no parent firm, independent firm revenues used.

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