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2013 FEB 14 A 10:40

February 13, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Citizen Petition

Re: Citizen Petition for clarification of Manufacturing Facility Generic Drug User Fees [GDUFA) Fees

Dear Sir / Madam,

Under 21 CFR Section 10.30, the undersigned, Chrai Associates Inc., (Chrai), submits this petition on behalf of its client, Square Pharmaceuticals Ltd, a foreign based company that has a manufacturing site located outside of US, to request the Commissioner of Food and Drugs to issue, amend or clarify the regulation and requirement for the payment of manufacturing facility fee (FDF Facility Fee) under Generic Drug User Fee Act [GDUFA, reference Section 101,Generic Drug User Fee Amendments of 2012],for a generic finished product manufacturing facility of a foreign based generic drug manufacturing company.

Chrai Associates, Inc. is the US Regulatory agent for Square Pharmaceutical Ltd. of Bangladesh. Our client has submitted its first generic application for a drug product that has patents listed in the FDA's Orange Book as expiring in December 2015. Our client has submitted an ANDA with a paragraph III certification in 2012 to

FDA-2013-P-0204

2013-1209
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ensure timely approval of this product due to the average approval time for ANDAs now stretching beyond 30 months.[1] Our client has no plans to submit any additional products over the next several months.

A. Action requested

(1) The petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.

(2) The petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.

(3) The petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.

(4) The petition request the Commissioner to issue clarification and revision of the following language included in the SEC. 102., Part 8, Section 744G (4)(A)(i) of GDUFA, from

Generic drug facility – Each person that owns a facility which is identified or intended to be identified at least one generic drug submission that is pending or approved to product one or more finished dosage forms shall be assessed an annual fee under the subsection (d) for each such facility

To

Generic drug facility – Each person that owns a facility which is identified or intended to be identified at least one generic drug submission that is pending or approved to product one or more finished dosage forms shall be assessed

[1] Summary of the generic pharmaceutical association testimony *before the energy and commerce subcommittee on health* united states house of representatives – April 18, 2012 "fda user fees 2012: how innovation helps patients and jobs

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ONE TIME ~~an annual~~ FDF facility fee until the approval of the first ANDA manufactured at the subject FDF facility under the subsection (d) for each such facility. This fee could be charged upon issuance of the approval letter or as a condition of approval of the ANDA. The facility will not be subjected to any other fees under GDUFA until the product manufactured at that facility is commercialized.

(5) The petition also requests commissioner to make a decision that our client should not be required to pay recurring annual FDF fees until a decision is reached on this petition

B. Statement of grounds

Introduction and Factual Background

Section 102 of GDUFA lists the generic drug user fees that will be applied to the review of generic abbreviated new drug applications [ANDA], Drug Master Files [DMF] for active ingredients [AI], prior approval supplements [PAS] and the and active ingredient and finished product

SEC. 102., Part 8, Section 744G (4)(A)(i) of the GDUFA includes the following language for generic drug facility fee:

> In general – Facilities indentified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug ..... shall be subject to fees as follows:
>
> Generic drug facility – Each person that owns a facility which is identified or intended to be identified at least one generic drug submission that is pending or approved to product one or more finished dosage forms shall be assessed an annual fee under the subsection (d) for each such facility

SEC. 102., Part 8, Section 744G (4)(C), the due date for these fees is as follows:

> (i) for fiscal year 2013 (i) For fiscal year 2013, the fees required by subparagraph (A) shall be paid within 45 calendar days of the publication of the notice required in subparagraph (B) except that if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the notice required by subparagraph (B), the fee shall be due 30 calendar days after the date that such an appropriations Act is enacted

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(ii) For each of fiscal years 2014 through 2017, such fees shall be due on the later of:

(I) the first business day after October 1 of each such year

Or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section

Unlike the Prescription Drug User Fee Act (PDUFA), GDUFA, provides NO exemptions for small businesses or first time sponsors of an ANDAs who do not have any drug products on the US market. Every manufacturer, small or large, immaterial of the number of products produced at that FDF facility is subjected to the same amount of GDUFA fees. The 2013 manufacturing fees for fiscal year 2013 are:

- Domestic FDF facility: $ $175,389
- Foreign FDF facility: $190,389

If these fees are to be paid annually, regardless of the outcome of the ANDA, it is quite burdensome for manufacturers especially those who do not have or do not anticipate having any revenue in US for next few years. Based upon the GDUFA performance goals, while the review cycle will be reduced in the 5 year cohort, the immediate favorable impact on the review timeline is unlikely. Also, for our client, under the best circumstances, the approval will be received in December 2015 and earliest the client will be able to market the product in US and be able to generate any revenue is January 2016.

Given this scenario and the specifics related to our client's situation, the manufacturing fees paid by our client for its finished product manufacturing facility before approval of the ANDA [assuming that the fee remains unchanged to the FY 2013 fees (which are not realistic, as the fees are likely to be increased each year)] will be as follows:

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Table 1 **Assessment of GDUFA FDF Manufacturing Site Fees During ANDA Review**		
GDUFA Fiscal Year	**Fees Due By**	**Amount (in $)**
2013	March 2013 [within 45 days of FR notice on 17 Jan 2013]	190, 389
2014	1 October 2013	190, 389
2015	1 October 2014	190, 389
2016	1 October 2015	190, 389
Total of FDF manufacturing facility fees paid prior to ANDA approval and any potential for revenue		**761, 556** Minimum in Best case scenario
Note – these fees do not include ANDA backlog review fees or any other fees		

For New Drugs approved under an NDA, under the PDUFA [Prescription Drug User Fee Act], the manufacturing facility fees are NOT charged unless the product is approved and commercialized by the NDA holder. The GDUFA provisions are much harsher and detrimental to the survival of a new company submitting its first ANDA and manufacturing its first generic product that is awaiting FDA approval. The payment of FDF facility fee requirement [as it is stated in the FDA Q&A] is burdensome and paralyzing to small size companies and / or foreign manufacturers and specifically to our client. The FDF manufacturing fees, similar to PDUFA, should only be collected upon commercialization of the first ANDA drug product from that site. If the FDA needs to cover the cost of pre-approval inspections etc., a separate fee could be charged and could be modeled after European regulations for charging the inspection related fees[2]

In any case, there must not be more than a onetime requirement for the payment of the FDF Manufacturing Fees. These fess may be collected either at time of submission, or approval or upon filing of an ANDA. These fees would adequately

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/12/WC500136431.pdf

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cover any Agency expenses that may be required for regulatory site related activities to support approval of the product.

Conclusion

The language currently included in the GDUFA should be amended, revised or clarified for the survival and benefit of the companies that are submitting their first (1st) ANDA application to the FDA from that FDF Manufacturing facility and these manufacturers / applicants should not be required to pay GDUFA user FDF manufacturing fees on an annual basis for several years [as they are undergoing ANDA review] prior to the ANDA approval and commercialization of the product produced at the FDF manufacturing site. The client will hold from paying any FDF manufacturing fees until a final decision is reached on this petition

C. Environmental impact

The actions requested in this petition will have no significant effect on the human environment.

D. Economic impact

This section is not applicable for this petition.

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E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely yours,

Priya Jambhekar
Chrai Associates, Inc.
16 Bodine Drive
Cranbury, NJ 08512
Tel 646-460-4660

Submitted in Duplicate

CC: Pending client ANDA

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01000

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SPH1

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City [redacted] State MA ZIP [redacted]

2 Your Internal Billing Reference

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2 or 3 Business Days

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