EFCG
EUROPEAN FINE CHEMICALS GROUP

Press Conference

GDUFA - Guy Villax
Member of the EFCG Board

at CPhI
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Frankfurt, Germany

Agenda

GDUFA

- Background and Negotiations
- Costs and Results
- Innovations
- Implications

What is GDUFA?

"To help FDA to ensure that participants in the US generic drug system comply with US quality standards, and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs, FDA and industry have jointly agreed to a comprehensive human generic drug user fee program, to be supplemental to traditional appropriated funding, that is focused on three key aims:

SAFETY – ACCESS –TRANSPARENCY …"

… from the minutes of the GDUF Negotiations Meeting of August 31, 2011.

As of today, Drug Product and Drug Substance manufacturers are inspected by the FDA on the basis of a historically grown system which does not represent anymore the real global picture of manufacturers, where in particular Asian providers have drammatically increased in number. Such plants are often not inspected due to many reasons such as the lack of resources to the FDA.

GDUFA will change the inspection and approval system moving to a risk-based approach to inspect plants and sites by considerably increasing the number of inspectors and supporting staff as well as tools, funded by the industry . Every inspected site and every new ANDA and DMF will be subject to a Generic Drug User Fee.

What is GDUFA?

- **GDUFA is in line with other user fee systems (PDUFA for Innovators, veterinary products i.e.) and to be jointly introduced with new fee programs for biosimilars and medical devices;**
- **GDUFA 1 - 5 year term – 1Oct2012 to 30Sept2017;**
- **US$ 300 Million for additional staff, IT and Science**
- **At end of 5 year expects to:**
  - **ANDA primary review time down from 31 months to 10 months,**
  - **GMP compliance inspections partity between Foreign and Domestic**
- **Will move from a pre-approval approach to a continuous surveillance approach;**
- **Frequency is risk-based inspection and will make use of input from other medicine agencies.**

Background data

- **For the second time fees for generics are discussed**
- **FDA started the public process in September 2010; EFCG joins in December; negotiations conclude in September.**
- **Industry represented by GPhA, SOCMA's BPTF and EFCG. EFCG involved for the 1° time, together with SOCMA's BPTF, deemed to represent the API industry during the GDUFA negotiations;**
- **17 face-to-face meetings in Washington (28 Feb-8 Sept).**

GDUFA – Cost

- Annual Budget of US$ 300 Million split:
  - 80:20 between Final Dosage Form (FDF) and API;
  - 70:30 between Application fees (DMFs/ANDAs) and Facility fees ;
- Combined facilities of FDF and APIs pay both facility fees;
- ANDAs which don't refer to a DMF, will pay the combined ANDA and DMF fees;
- The API industry globally pay $60m/annually

GDUFA – Results

Planned results at end of 5 years:

- backlog of ANDAs dealt with
- ANDAs primary review cycle in 10 months (currently 31)
- Parity between domestic and foreign inspections:

GDUFA – ...

EFCG unable to convince FDA to seek efficiencies by collaborating with other agencies in order to pool knowledge and share the burden of inspections

EFCG looked to negotiate savings by avoiding FDA inspections in Europe through a mechanism of mutual recognition.

That said, GDUFA is a major step forward, possibly the most significant step since Waxman Hatch act

GDUFA – what we may get

Creation of a DMF database with "available for reference" status;

FDA will look to address easy-to-resolve deficiencies by telephone prior to issue of deficiency letter;

FDA will communicate all deficiencies related to the DMF in one single letter covering all disciplines;

Offer of one teleconference between DMF holder and FDA to clarify deficiency letter points;

Parity of inspections between foreign and domestic API manufacturers, risk-based surveillance system becomes primary approach; PAIs may still apply;

GDUFA – if you don't pay...

- The DMF will not be listed as "available for reference" and consequently the ANDA will not be received by the FDA for review;

- The Facility will be identified publicly and no new ANDAs (including supplements) using material therein produced will be received;

- FDA will refuse to receive or approve ANDAs referring to such facility (including supplements or amendments);

- All APIs or FDF manufactured in those facilities will be classified as misbranded (502(aa)), and therefore, the entry into the USA may be forbidden;

GDUFA – why this is good

- Promotes faster access to lower cost and high quality medicines
- Accelerates approval process, speed to market
- Levels the playing field

- EFCG and APIC have publicly welcomed user fees since 2004 as a means to achieve inspection parity between foriegn and domestic, we are pleased that the FDA has taken us up on this.

Questions ?

NB:

This presentation only addresses the main API related issues, some items are not covered. Dosage form and ANDA aspects not covered at all. Please await for the final documents to be published by FDA.

Thank you
for your attention

- For more information please contact:

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