F A C S I M I L E

Medion Diagnostics

7473 '03 JUL 21 A9:42

Date:	July 11, 2003
To:	Diane Mahoney – CBER – Fax: 001 301 827 04 40
cc:	Sheryl Kochman - 001 301 827 35 34
	Candace Williams – Olympus – 001 972 432 95 32
From:	Dr. Hans Dieringer
Phone:	+41 (26) 4928-501
Fax:	+41 (26) 4928-657

Total Pages Including Cover Sheet:

Re: Medical Device User Fee and Modernization Act of 2002

Dear Mrs. Mahoney,

Medion Diagnostics, a manufacturer of blood grouping reagents and reagent red cells located in Switzerland is writing to you in order to send you some comments on the Medical Device User Fee and Modernization Act of 2002.

First of all Medion Diagnostics welcomes the initiative and effort of FDA to continuously improve and shorten the review for submissions and to shorten the time for a final decision on submissions made for Medical Devices.

In general, Medion Diagnostics can also accept the principle of financial contribution for such review and evaluation.

However, we believe that the fees for such review and evaluation should be linked to the complexity of the subject and should relate to the economical potential of a product.

Too high fees will keep new innovative products off the market unless there is a significant market potential and the company can afford to make the additional investment for the new product. This could lead to a situation where only a few large companies are providing products to the US market and as a result they will have kind of a monopoly in terms of pricing and quality.

In our market segment, e.g. there are basically only two companies left on the market (Ortho Clinical Diagnostics and Immucor). Our market share (as company no. 3) is less than 1%

Medion Diagnostics GmbH Bonnstrasse 9 CH-3186 Düdingen / Switzerland
Tel: +41 (26) 4928 511 Fax: +41 (26) 4928 600

02N-0534

C33

F A C S I M I L E

and we are not even recognized by competition. These two companies left are now in a position to totally control the market. In order to extend our current product portfolio, the financial hurdle is extremely high for companies like us. Improvement of tests or the introduction of new tests is extremely costly as each new test requires a new BLA or a supplement which, in our case, results in the same cost. Also, there is no need to continuously improve the tests provided as there is basically no competition. This, as a consequence, could lead to a situation where US customers would have to use and apply old fashioned test systems whereas, due to competitive pressure, state of the art systems would be sold outside US.

There is another aspect, I would like to draw your attention to and that is the Small Business Qualification. The guidance specifies that, in order to qualify as a small business, you need to have a Federal income tax return. Medion Diagnostics holds its own Biologics License, however it distributes its products through a domestic distributor. That means that we will never qualify as a small manufacturer and will have to pay for each new test parameter the full fee of $ 154'000 as an upfront payment without having sold a single vial. This prohibits us and we believe also other companies to enter the U.S. market.

As a result we would recommend to clearly differentiate user fees in relation to the complexity of the submission, taking into consideration also the economical potential of a particular product. A new state-of-the-art HIV test has a different economical potential than an Anti-Co or a special concentration of Reagent Red Cells in a particular diluent which is used by a limited number of highly specialized labs but which is important to have in order to avoid transfusion problems. Also, foreign manufacturers which do not have an own subsidiary in US and therefore cannot base their size on a Federal income tax return should have the opportunity to qualify as a small manufacturer through other means.

This would not only increase competition in pricing but would also create an innovative environment and assure that state-of-the-art products are introduced also for niche markets where high user fees would otherwise be cost prohibitive.

Medion Diagnostics is convinced that the IvD market requires continuous improvement and change and hopes that extreme user fees do not stand in the way of such progress.

We very much appreciate the opportunity to provide you with our thoughts and remain,

sincerely yours,

Dr. Hans Dieringer
Managing Director