



ABBOTT

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Tuesday, June 4, 2002

Tommy Thompson, Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments on May 21 Letter from Public Citizen Health
Research Group urging criminal charges against Abbott
Laboratories and referring to *Request to Ban Meridia*® (FDA
Docket No. 02P-0120/CP1)

Dear Secretary Thompson:

Abbott Laboratories (Abbott) is writing in opposition to the latest communication from Public Citizen Health Research Group (HRG), dated May 21, 2002, urging you "to bring criminal charges against Abbott Laboratories for illegally withholding from the FDA important information concerning eight deaths and other adverse effects of...sibutramine (Meridia)...".

Abbott's April 26 submission to this docket fully addresses the safety of Meridia. As you know, on March 19, HRG submitted a petition to you and the Food and Drug Administration (FDA) seeking the withdrawal of approval and immediate suspension from the market of Meridia® (sibutramine hydrochloride monohydrate CIV capsules). On April 26, Abbott submitted to you, and to FDA, comments in opposition to the HRG petition. In those comments we established that HRG's petition is without merit and does not objectively represent the safety, efficacy, or regulatory review process that led to the approval of Meridia. As we stated in the comments' conclusion, and as we continue to maintain,

The regulatory review of Meridia by the FDA was robust and scientifically driven. The issues raised during the review process were thoroughly and responsibly addressed. ...[T]he efficacy of Meridia, in study after study, is of a magnitude and durability that is clinically important in the management of obesity. We have shown that the safety of Meridia is well-characterized and transparently represented in the product information, providing responsible guidance to both the appropriate use of Meridia as well as its potential risks. The HRG Petition is thus at odds with an overwhelming body of data.

Abbott remains fully confident of the safety and effectiveness of Meridia, which has been extensively and thoroughly studied. This safe and effective product has been used by more than 8.5 million patients in more than 70 countries since its approval in 1997.

02P-0120 The latest from HRG, its May 21 letter posted on the Public Citizen website, further distorts the facts about Meridia by misrepresenting certain observations FDA made following a recent inspection of sibutramine safety data by FDA's Chicago District Office. We are dismayed that physicians and patients may, once again, be unduly alarmed by HRG's irresponsible

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allegations; thus, there is a need, once again, to set the record straight regarding the untruths HRG continues to propagate regarding Meridia.

FDA's inspectional observations have no bearing on the conclusions Abbott and FDA have made based on the extensive medical analyses that have been conducted and reported regarding Meridia. These analyses continue to support the favorable risk benefit profile of Meridia.

Furthermore, Abbott is confident that all confirmed fatalities reported to the company coincident with Meridia use have been appropriately reported to authorities, as required by the regulations. In its May 21 letter, HRG alleges that Abbott failed to report a patient death. In point of fact, Abbott's investigation of the records related to the alleged unreported death indicates that the event was termed a rumor by the person who contacted the company. Further investigation failed to substantiate this rumor. Of course, Abbott will continue to report adverse event data consistent with its regulatory obligations.

Abbott, on April 18, fully responded to FDA's observations, none of which impacted product safety. Regarding the three cases HRG alleges it found where Abbott was late in notifying FDA, HRG perpetuates its practice of levying serious accusations without supporting its charges with any documentation whatsoever. (HRG's March 19 Citizen Petition likewise lacked supporting documentation). Abbott cannot respond to HRG's charges without knowing specifically what alleged incidents HRG is referring to. These alleged incidents were not part of FDA's observations following the inspection of the sibutramine safety data.

The charges by Public Citizen HRG irresponsibly alarm patients and physicians by misrepresenting FDA's observations. These charges do a major disservice to the hundreds of thousands of patients and their physicians who are treating the medical condition of obesity with Meridia, an important option for the treatment of obesity, which has become an international epidemic. As was explained in Abbott's response to HRG's citizen petition, obesity contributes significantly to other serious medical conditions, such as Type 2 diabetes, cardiovascular diseases, cancer and respiratory conditions.

We again respectfully request the prompt and unqualified denial of HRG's March 19 citizen petition and we appreciate your careful consideration of this matter.

Sincerely,



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Global Pharmaceutical Development
Abbott Laboratories

cc FDA Docket No. 02P-0120/CP1
FDA Deputy Commissioner Lester M. Crawford