

April 7, 2003

Dockets Management Branch, (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Buford Pusser
342 Pusser Street
Adamsville, Tennessee 38310

Re: **[Docket No. 02N-0534]/MDUFMA Comment**

Dear Assistant Commissioner Dotzel,

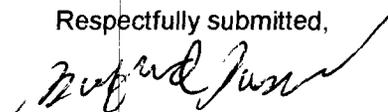
It looks like either your doctors or your financial people are making the decisions about the user fee program without any involvement of the regulators that know the review programs. Everyone knows that it is a tough job to decide when you need to get FDA approval to sell a device. While you have guidance documents to help us out, you need a Ph.D. to understand them and a crystal ball to get the same answer as FDA.

When I was with the FDA, we were the "arbiters" of when a 510(k) or PMA supplement had to be submitted. Sometimes someone would complain about a device being sold without FDA approval and we would look into it. We looked at the device and made a cut as to whether a marketing application should have been submitted. It was pretty easy and did not take too long. We did the same thing when we received a 510(k) or PMA and did not think that it was required. We didn't have as many 510(k) exempt devices in my day, but when we got a 510(k) for one we wrote to the company and told them it was exempt. If I am right, the regulations told us to handle this situation this way.

From what I have been able to tell, the FDA intends to "take the money and run" when they get a 510(k) or PMA that was submitted by mistake. Just last week, I asked an ODE Branch Chief what they would do if a company submitted a 510(k) for a 510(k) exempt device. I was told that this issue was raised at a recent training course where a Deputy Center Director stated that "no user fee money would ever be returned to companies." He said that the words may not be an exact quote but the message was clear, that is, if a 510(k) comes in for an exempt device, review it and keep the fee. I asked him if anything was in writing. He said "no" but went on to say that he thought the training was taped and there was a record. I asked him if I sent in a 510(k) for an ambulance would he review it and keep the fee. He said he would write me a letter telling me an ambulance was not regulated by FDA, but only after checking to see that my check cleared the bank. We laughed!

Now maybe I am all wrong and you don't intend to charge user fees for 510(k)s and PMAs that are not required to be sent in to the FDA. If you plan on rebating the money when a 510(k) is received and is not needed, you need to tell the reviewers what they should do. If you plan on keeping the money, you better get prepared to do some explaining. Unless the President has asked you to balance the federal budget or support the war effort by taking all the money you can get for doing work that doesn't take long to do and is not required, it is just a matter of time until you are taken to task. I suspect that OMB will have a thing to say about your practices

Respectfully submitted,



Buford Pusser

02N-0534

C22