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STAKEHOLDER MEETING ON THE POSSIBLE IMPLEMENTATION  
OF TWO PERFORMANCE GOALS

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## 1 P R O C E E D I N G S

2 (9:00 a.m.)

3 MR. BARNETT: I'd like to welcome  
4 you to this public meeting to discuss a  
5 specific aspect of the Medical Device User  
6 Fee and Modernization Act, or MDUFMA as we  
7 all know it.

8 Today's meeting will focus on two  
9 of the review performance goals that FDA  
10 agreed to consider for FY 2007, when MDUFMA's  
11 performance goals were drafted back in 2002.  
12 When the FDA, stakeholders, and Congress  
13 drafted MDUFMA's performance goals, everyone  
14 agreed these two goals were potentially very  
15 challenging. And so rather than commit FDA  
16 to goals that it might not be able to make,  
17 it was agreed that FDA would review its  
18 progress and would hold a public meeting  
19 following the close of FY 2005 to help decide  
20 whether it would be appropriate to implement  
21 these goals for FY 2007. And of course  
22 that's why we're here today.

1           The first of those two goals is  
2    that 50 percent of the pre-market approval  
3    applications received in fiscal year 2007  
4    will have an FDA decision in 180 days. And  
5    the second goal is that 80 percent of  
6    pre-market notifications, or 510(k)s, will  
7    have an FDA decision in 90 days.

8           If FDA decides that one or both of  
9    these goals are not appropriate, then we must  
10   submit a report to Congress providing our  
11   rationale for not implementing the goal.

12           What we need from you today are  
13    your thoughts about the feasibility and  
14    desirability of implementing these two  
15    performance goals in fiscal year 2007. In  
16    order to hear you, we've assembled a panel of  
17    FDA MDUFMA experts. Let me introduce them.

18           Linda Kahan is deputy director of  
19    FDA's Center for Devices and Radiological  
20    Health. Dr. Donna-Bea Tillman is Director of  
21    the center's office of device evaluation.  
22    And Diane Maloney is Associate Director for

1 Policy in FDA's Center for Biologics  
2 Evaluation and Research.

3 Now let me tell you about the  
4 format for today's meeting. First I'm going  
5 to ask Linda to fill us in on the history of  
6 these two performance goals and what the  
7 framers of the MDUFMA legislation had in mind  
8 when they developed them.

9 Then Donna-Bea Tillman is going to  
10 discuss what we've done to meet the various  
11 MDUFMA goals for the pre-market evaluation  
12 and approval of medical devices, and our  
13 track record in meeting those goals.

14 Donna-Bea will then go on to explain FDA's  
15 position on whether or not to implement these  
16 two particular performance goals in fiscal  
17 year 2007, and she'll provide the rationale  
18 for that position.

19 Once that happens, we'll open the  
20 floor and hear your comments on whether or  
21 not we should implement these two goals in  
22 fiscal year 2007. Four people have signed up

1 in advance to speak, and we'll hear from them  
2 first. Then we'll take comments from anyone  
3 else who'd like to speak. The meeting is  
4 being recorded by a stenographer, so we'll  
5 have a permanent record of what you say here  
6 today.

7 Before we begin, let me give you a  
8 couple of simple ground rules for when you  
9 present your comments. First, because of the  
10 very specific nature of this meeting, we want  
11 comments only on the two performance goals  
12 under consideration.

13 This is not a meeting about FDA's  
14 medical device program in general. In fact  
15 it's not even about MDUFMA in general. It's  
16 about two specific MDUFMA performance goals  
17 relating to pre-market approvals and  
18 pre-market notifications. As we explained in  
19 the Federal Register Notice announcing this  
20 meeting, it's in that highly focused area  
21 where we're asking for your thoughts.

22 The second simple ground rule is

1 that presentations from the floor should last  
2 no longer than 10 minutes each. I'll watch  
3 the time, and I'll give you a signal when you  
4 have two minutes remaining, and then ask you  
5 to wind it up at the 10-minute mark.

6 Now that we've talked about why  
7 we're here, what we want to accomplish, and  
8 how we'll go about it, let me ask Linda Kahan  
9 for some opening comments.

10 MS. KAHAN: Thank you, Mark. And  
11 thank you all for coming to today's meeting.  
12 Meetings with stakeholders about MDUFMA are  
13 an important part of making the program work,  
14 and this is one of a number of meetings we've  
15 had. We've held annual stakeholder meetings  
16 each fall since the passage of MDUFMA, and  
17 other meetings at regular intervals over the  
18 past three years.

19 In addition to today's meeting, we  
20 look forward to a broader public meeting this  
21 coming October to discuss possible  
22 performance goals and other initiatives for

1 MDUFMA II, the reauthorization of MDUFMA that  
2 we're hoping for, since this program ends in  
3 2007.

4 As Mark noted, in 2002, FDA,  
5 stakeholders, and Congress negotiated a  
6 comprehensive set of goals for medical device  
7 applications that included both cycle goals  
8 and decision goals.

9 The purpose was easy to  
10 understand -- industry wanted better  
11 performance and greater predictability about  
12 how long it would take FDA to review a  
13 product and reach a final decision -- and FDA  
14 wanted additional resources that would make  
15 it possible for us to deliver those  
16 improvements.

17 Among the goals that were  
18 negotiated were the two stretch goals we are  
19 discussing today.

20 Before we get to the stretch goals,  
21 let me say a few words about the MDUFMA cycle  
22 and decision goals. The target for the

1 decision goals focused on 90 FDA days for a  
2 510(k) and 320 days for a PMA.

3           The target of the cycle goals  
4 varied, but the intent of all the cycle goals  
5 was to ensure that in situations where  
6 applications were incomplete, the agency  
7 would provide feedback early on -- so that  
8 companies could do what was necessary to make  
9 a product approvable or establish substantial  
10 equivalence as quickly as possible.

11           The primary purpose of both cycle  
12 and decision goals was to improve FDA  
13 performance on applications that were taking  
14 too long -- the 510(k)s that were taking more  
15 than 90 FDA days and the PMAs that were  
16 taking more than 320 days.

17           Now for the stretch goals. There  
18 are others in this room besides me who were  
19 around the table when these stretch goals  
20 were discussed as part of MDUFMA negotiations  
21 back in 2002. Those folks already understand  
22 the background and purpose of those goals,

1 but for the rest of you, I'd like to put  
2 these goals in context and explain a bit  
3 about their history and intent.

4 The two stretch goals for 2007 are  
5 somewhat different than the typical cycle and  
6 decision goals. Let's start with the PMA  
7 stretch goal of making 50 percent of FDA  
8 decisions within 180 days.

9 FDA receives fewer PMAs than many  
10 other types of applications, but the  
11 distribution of review times before MDUFMA  
12 was very wide. The purpose of the stretch  
13 goal was not only to show improvement in  
14 performance in our review of some PMAs, but  
15 the idea was to --

16 SPEAKER: Linda, are you still  
17 there?

18 MS. KAHAN: Yes. Can you hear now?  
19 Can you hear me now? This is Linda.

20 SPEAKER: Yes.

21 MS. KAHAN: Okay, great. What I  
22 was saying was that the point of the stretch

1 goal was not only to show improvement in  
2 performance in our review of some PMAs, but  
3 to improve the performance of the entire  
4 cohort. In other words, we wanted to shift  
5 the entire distribution of FDA decisions on  
6 PMAs towards the faster end of the scale.

7 In the case of the 510(k) stretch  
8 goal, FDA's review found performance of  
9 510(k)s was acknowledged to be pretty good,  
10 even at the time we were negotiating MDUFMA.  
11 But stakeholders realized that shifting a  
12 major portion of these 510(k)s to the faster  
13 review times of less than 90 days could be  
14 challenging, for primarily two reasons.

15 One is that we have a huge number  
16 of 510(k)s, literally in the thousands, and  
17 because many of the submitters of 510(k)s are  
18 smaller companies that may have less  
19 experience in working with regulated industry  
20 and with working with FDA.

21 So given the uncertainty, the  
22 510(k) stretch goal was developed for fiscal

1 year 2007 to give the agency time to gear up.

2 So that's why it was pegged at 2007. And

3 that's going to be 80 percent of 510(k) final

4 decisions within 90 days, and a final

5 decision for a 510(k) is substantially

6 equivalent or not a substantial equivalent.

7           The legislation recognized, as Mark  
8 mentioned, that FDA might not be able to meet  
9 the two stretch goals for 2007. And in fact,  
10 that was assuming back then that FDA would  
11 receive the amount of dollars that were  
12 authorized, as well as the amount of user  
13 fees that were authorized.

14           And as all of you in the room  
15 probably know, that didn't happen. Neither  
16 the appropriations nor the amount of user  
17 fees met the levels that industry and FDA had  
18 anticipated. And MDUFSA, the Medical Device  
19 User Fee Stability Act, which went into  
20 effect last year, actually reduced the amount  
21 of total monies that the FDA will be getting  
22 for this program.

1           So even before the reduction in  
2    what we were expecting and industry was  
3    expecting us to have, there was some concern  
4    about these two stretch goals. So because  
5    the legislation recognized that the stretch  
6    goals could be problematic, it built in the  
7    provision that brings us together today.

8           If FDA thought it was a question  
9    about not being able to meet either or both  
10   of these goals, we were going to have this  
11   meeting where we could discuss it with you  
12   and we could hear your feedback about it.  
13   And then FDA is required to send Congress a  
14   report explaining its decision in the recent  
15   stretch decision.

16           The agency does believe that it's  
17   on track to meet the 510(k) stretch goal for  
18   2007. But for reasons that Dr. Tillman will  
19   discuss in just a minute, FDA does not  
20   believe that it can meet the PMA stretch goal  
21   for 2007, and also doesn't believe that it  
22   would be a good idea for us to develop

1 resources to that particular target as we go  
2 forward for next year. And that's really the  
3 focus of our discussion today.

4 So without further ado, I'm going  
5 to turn it over to Donna-Bea.

6 DR. TILLMAN: Good morning. Can  
7 the people on the phone hear me?

8 SPEAKER: I can.

9 DR. TILLMAN: Okay. I'm going to  
10 take that as a yes. All right, this morning  
11 I'm here to give an update on FDA's  
12 performance in meeting the MDUFMA stretch  
13 goals. I wanted to just start off because we  
14 can't say it enough to just remind you of  
15 what the objectives of MDUFMA are. The idea  
16 behind MDUFMA was that the Agency would get  
17 additional resources and that these resources  
18 would result in a sustainable review program  
19 for medical devices, and that that would mean  
20 that there would be increased predictability  
21 in review time and increased timeliness in  
22 the review process.

1           The overall goal of MDUFMA was to  
2    get safer and effective products to the  
3    market more quickly. And I'd like to spend  
4    the first couple of minutes of my talk going  
5    through a little bit of data that shows how  
6    we've been able to meet this overall  
7    objective of MDUFMA. So first of all, we are  
8    meeting or exceeding nearly all of our  
9    agreed-upon performance goals. With the  
10   exception of the two stretch goals I'm going  
11   to talk about in a minute, if you look at the  
12   other performance goals, except for those  
13   where there are very small numbers -- and  
14   sometimes meeting or not meeting hinges on  
15   one submission, because you may have two or  
16   three, and you've got to achieve the goal on  
17   all three of them in order to get a  
18   100 percent versus if you only do two, you  
19   get 66 percent.

20           We are meeting nearly all of the  
21   agreed-upon performance goals. And we  
22   believe that this has indeed brought greater

1 consistency and predictability to the review  
2 program. And I'm going to show you actually  
3 some data that gets at this in just a moment.

4 We also believe that the current  
5 performance goal structure doesn't completely  
6 capture what MDUFMA has meant for the Medical  
7 Device Review Program.

8 And in that vein, I wanted to show  
9 you a couple of slides that I think more  
10 fully capture what MDUFMA has meant for the  
11 pre-market review program for medical  
12 devices.

13 Now, this slide here is a slide  
14 that looks at our 510(k) program. And what  
15 it is is a plot of the total days that it  
16 takes for a 510(k) to be reviewed. So this  
17 is the time between when the 510(k) comes in  
18 the door and the time at which the final  
19 decision is made. It captures both FDA time  
20 and what we call the medical manufacturer  
21 time. And what this slide shows is that as a  
22 result of implementing some of the processes

1 that I'm going to talk about that came with  
2 MDUFMA, we have been able to show a steady  
3 decrease in the total time which it takes a  
4 510(k) to reach a final decision.

5 And it took us to 2003 or so to  
6 start getting our MDUFMA program geared up,  
7 and you can see from 2003 through 2004 and  
8 2005, you can see there is a steady decline  
9 in the average total elapsed time. These  
10 slides are CDRH data -- by the way, just  
11 wanted to note that the CBER data is  
12 consistent, the numbers are smaller, but they  
13 don't change the bottom line.

14 This slide shows a similar but not  
15 quite as compelling result in the PMA  
16 program. This slide shows the average total  
17 time between when the PMA comes in and a  
18 final MDUFMA decision is reached, and that's  
19 an approval, approvable or not approvable.  
20 And you can see that once again, there was a  
21 plateau before MDUFMA and into the earlier  
22 phases of MDUFMA implementation, and then in

1 2004, you can see those times are starting to  
2 trend down. I will note that for PMAs,  
3 because it takes a long time to reach a PMA  
4 decision, we don't have any solid data for  
5 2005. So we don't have quite as much of a  
6 strong story to tell here because we don't  
7 have the 2005 data yet. But we expect to see  
8 the same kind of decrease in total times.

9           And then finally, in our 180-day  
10 PMA supplement program, we've seen a similar  
11 story. Once again, the total days between  
12 the time that a PMA supplement is received  
13 and the time in which a final decision is  
14 reached has decreased over the course of the  
15 implementation of MDUFMA.

16           So what these charts show is that  
17 not only has FDA been able to meet the  
18 agreed-upon MDUFMA performance goals, we've  
19 also been able to achieve the objective of  
20 MDUFMA, which is to get safe and effective  
21 products to the market more quickly.

22           So how do we make this happen?

1 What do we do to implement MDUFMA -- and I'm  
2 going to spend a little bit of time talking  
3 about this, because it directly relates to  
4 our ability to meet the stretch goals.

5 So in the 510(k) program, we  
6 started off by looking at our 510(k) business  
7 process and thinking about what we would need  
8 to do in order to develop a 510(k) business  
9 process that would enable us to meet both the  
10 cycle and the decision goals for 510(k)s.

11 And this is a slide that we've  
12 shown numerous times over the past couple of  
13 years showing the new business process that  
14 we developed, where we basically told our  
15 staff that within an initial FDA review  
16 period of -- for 510(k) is around 45 days,  
17 they needed to make a decision about whether  
18 there was enough information to reach a final  
19 decision in the 90-day cycle or whether they  
20 needed to put the file back on hold and wait  
21 for additional information.

22 And so you can see we've got this

1 sort of iterative review process. And then  
2 the reason we needed to develop this process  
3 is because we had cycle goals that we had to  
4 meet, as well as total decision goals we had  
5 to meet. As a result of implementing this  
6 new business process, we were able to meet  
7 both the cycle and the decision goals for  
8 510(k).

9           You can see in FY '03, which is  
10 somewhat sort of baseline data, FY '04 to FY  
11 '05, that we've been able to increase the  
12 percentage of 510(k)s that have final  
13 decisions within 90 days as the decision  
14 goals, and we've also been able to meet the  
15 cycle goals -- the first action and the  
16 second action goals as well.

17           And the other thing that we've been  
18 able to accomplish by putting together this  
19 more standardized business process is that  
20 goal of increase in predictability of review  
21 time.

22           This slide is a little complex.

1 I'm going to take a minute to explain it.  
2 What this shows is for each fiscal year,  
3 across the bottom axis, the percentage of  
4 CDRH 510(k)s that were reviewed within 90  
5 total FDA days.

6 And what we did is we went back and  
7 looked at the performance of each of our  
8 reviewing branches. And the bottom line  
9 shows the branch that had the longest review  
10 times -- the worst performance, if you will,  
11 and the upper line shows the range of  
12 performance for our best-performing branches.  
13 And what you can see is that prior to the  
14 implementation of MDUFMA, it was a pretty  
15 good gap between our lower-performing  
16 branches and our higher-performing branches.

17 And as a result of implementing  
18 these more standard business processes across  
19 the center, we were able to close that gap.  
20 We were able to bring the branches that were  
21 performing as well up to the level of the  
22 better-performing branches, and in fact we

1 were also able to increase the performance of  
2 the better-performing branches.

3 So what we've done is we've been  
4 able to increase the predictability of the  
5 510(k) review process as well.

6 Now what about the 510(k) stretch  
7 goal? As Linda has already mentioned -- and  
8 Mark -- the stretch goal for 510(k)s is that  
9 in FY '07, 80 percent of 510(k)s will have a  
10 final decision in 90 days.

11 And as you've already seen, we are  
12 meeting this goal. This chart shows the  
13 510(k) stretch goal graphically. You can see  
14 that in 2002-2003, we were below the goal,  
15 and then as a result of implementing our new  
16 510(k) business process, not only are we  
17 meeting the goal, we are actually exceeding  
18 that goal.

19 That goal doesn't actually come  
20 into effect until FY '07. But you can see  
21 that even in FY '05, we're still quite a bit  
22 above that goal. And we anticipate that we

1 will be able to meet that goal in FY '07,  
2 because we don't see any reason why our  
3 performance won't continue to maintain its  
4 current levels.

5           So why were we able to meet this  
6 510(k) stretch goal even in 2004? Well, for  
7 510(k)s, the stretch goal is simply an  
8 extension of our decision goal. And as I  
9 mentioned before, we developed a business  
10 process that would enable us to meet both the  
11 cycle goals and the decision goals for  
12 510(k)s, and by implementing that new  
13 business process, we were able to meet the  
14 stretch goals.

15           And that's the story for 510(k)s.

16           For PMAs, as you're going to see,  
17 there is a very different situation. And the  
18 reason why is that because unlike the 510(k)  
19 stretch goal, the PMA stretch goal is not  
20 simply an extension of the decision goal.

21           When we sat down in 2002 and  
22 thought about how we were going to meet the

1 PMA goals, both the decision goals and the  
2 cycle goals, once again, we developed a new  
3 PMA business process that would enable us to  
4 meet both of these goals.

5 And this slide sort of shows all  
6 the different activities that have to occur  
7 during the course of a PMA review, and how we  
8 planned it out so that we could meet both the  
9 cycle goals for PMAs and the final decision  
10 goal of 320 days.

11 As a result, we're meeting both the  
12 cycle and the decision goals for PMAs as  
13 well. This slide shows '03 and '04 data  
14 because the '05 data isn't complete enough to  
15 make it meaningful, but I've shown you the  
16 FY '05, actually FY '06 goals here.

17 And as you can see, for the  
18 decision goal of less than 320 days and for  
19 the major what we call cycle goals, FDA is  
20 meeting both the cycle and the decision goals  
21 for the original PMA program.

22 Now what about the stretch goal for

1 PMA's? Well, for PMA's, the stretch goal is  
2 that 50 percent of PMA's will have a final  
3 decision in 180 days. And as Linda already  
4 mentioned, we are not meeting that goal.

5 If you look at our performance in  
6 2002, you can see -- this is FDA performance,  
7 this is CBER and CDRH data combined, that we  
8 were below that stretch goal in 2002, and in  
9 fact, our performance has, if anything, got  
10 worse.

11 So we do not believe that we're in  
12 a position to meet that stretch goal in 2007.  
13 So what's going on here, why aren't we  
14 meeting the PMA stretch goal? Well, we  
15 designed a business process that would enable  
16 us to meet the cycle and the decision goals.  
17 And as I've already shown you, we were very  
18 successful in doing that. That business  
19 process enabled us to meet the cycle and the  
20 decision goals.

21 Now, one of the implications of  
22 that new business process was that we had to

1 make decisions earlier on in the review  
2 process. And so if we were going to issue a  
3 major deficiency letter, in order to be sure  
4 that we got it out by 150 days, we had to be  
5 deciding whether we needed a major deficiency  
6 letter earlier on. As a result of the need  
7 to make that decision earlier on, we  
8 generally started erring on the conservative  
9 side, and if we thought we would probably  
10 need one, we were issuing a major deficiency  
11 letter.

12           So in order to meet the cycle  
13 goals, we had to be a little more  
14 conservative in our thinking about the need  
15 for a major deficiency letter. And as a  
16 result, we were more likely to issue a major  
17 deficiency letter than we had been in the  
18 past.

19           So as a result, the number of first  
20 action major deficiency letters has  
21 increased. It was 51 percent in 2002, and  
22 it's 68 percent in 2004.

1                   So by increasing the number of PMAs  
2     that get a first action major deficiency  
3     letter, we're decreasing the number of PMAs  
4     that are actually done in 180 days. So we  
5     believe that the problems that we're seeing  
6     here with our inability to meet both the  
7     stretch goals and the cycle on the decision  
8     goals are due to the delay in which the  
9     MDUFMA goals are structured, and that in  
10    order to fix these, we're going to need to  
11    have statutory changes, because the goals are  
12    part of the statute.

13                   So in conclusion, we are meeting or  
14    exceeding nearly all of the MDUFMA  
15    performance goals, including the FY '07  
16    510(k) stretch goal. However, given the  
17    structure of the current cycle and decision  
18    goals for PMAs which are set in the statute,  
19    we are not in a position to meet the PMA  
20    stretch goal.

21                   Because we think that implementing  
22    this PMA stretch goal would adversely affect

1 the PMA program, as Linda mentioned, one way  
2 for us to meet an early decision goal is to  
3 make a negative decision, which is not in  
4 anybody's -- I think, best interests.

5 We do not intend to implement the  
6 PMA stretch goal in FY '07.

7 We are very interested in hearing  
8 your thoughts about the data that I  
9 presented.

10 Thank you.

11 MR. BARNETT: Thank you, and now it  
12 is time to hear your thoughts. We have four  
13 people who have signed up in advance to  
14 speak. Let me ask Janet Trunzo from AdvaMed  
15 to come up and do her thing first.

16 MS. TRUNZO: I'm willing to wait on  
17 my time.

18 MR. BARNETT: You want to wait?  
19 Okay. David Douglass of the National Venture  
20 Capital Association.

21 Mr. Douglass?

22 MR. DOUGLASS: Thank you. Are

1 these presentations in any order?

2 SPEAKER: Let's see. Do you have  
3 his presentation on here anywhere?

4 Where is Cynthia? She said she  
5 would have it available.

6 (Pause)

7 MR. DOUGLASS: Thank you very much  
8 for allowing me to be here. My name is David  
9 Douglass, and I'm the general partner of a  
10 venture capital firm called Delphi Ventures.  
11 I'm here to represent the National Venture  
12 Capital Association.

13 And we think that it's important to  
14 be here because venture capital in our  
15 industry has become a new stakeholder, in  
16 that we're important in the stimulation of  
17 newfound technology, advancing these  
18 technologies and helping our companies get  
19 through the FDA process. And in fact, in the  
20 second half of the lives of most of us here,  
21 many of the technologies that we will consume  
22 will have been venture capital-sponsored or

1 financed: Technologies in cardiology,  
2 neurology, orthopedics, gynecology, industry.

3 So I wanted to talk a little bit  
4 about the role of venture capital in medical  
5 device innovation, and also comment on our  
6 recommendations on certain MDUFMA performance  
7 goals. And clearly, our goal is to help  
8 provide a streamlined pathway for the  
9 commercialization of medical technologies.

10 And these are technologies that save and  
11 improve the lives of patients and also help  
12 cut down the costs of health care.

13 I know within our organization, we  
14 have financed over 100 medical device  
15 companies. We had 40 of these companies got  
16 acquired by large companies, and 41 get  
17 acquired -- and our whole mantra is trying to  
18 identify surgical procedures, find smart  
19 people to develop less surgical and minimally  
20 invasive technologies to accomplish these  
21 procedures, and also less invasive diagnostic  
22 technologies.

1           Just a little bit on our role as  
2    venture capitalists is we do create new  
3    companies that are based on novel  
4    technologies both in high tech and medical.  
5    We often start these companies up from an  
6    idea. We'll put in \$500,000 to a \$1 million,  
7    get a prototype developed, and then help  
8    arrange financing that can range from  
9    anywhere from \$10 million to \$30 million.

10           Most of our role after the  
11   financing of these companies is to serve as  
12   directors of these companies where we recruit  
13   management teams as well as technical teams.

14           Most of us in the venture capital  
15   business have been entrepreneurs or  
16   technologists themselves. Just as a  
17   snapshot, the National Venture Capital  
18   Association represents just under 500 venture  
19   capital firms. But these 500 firms represent  
20   over 90 percent of all the venture capital  
21   under management.

22           And over the last 35 years, the

1 number of venture firms have grown from 28 to  
2 just under 900, representing just under \$300  
3 billion of cash.

4 In terms our sources of financing,  
5 venture capitalists go out and raise  
6 money -- it's a blind pool -- money is  
7 committed to our funds, and then we turn  
8 around and make the investment decisions  
9 independent from our limited partners.

10 And I would say, over the last 10  
11 to 15 years, venture capital has become a  
12 significant investment class, representing  
13 often five percent of an institution's  
14 overall cash available to invest.

15 Many of these sources of our funds  
16 include endowments and pension funds,  
17 corporations, insurance companies and wealthy  
18 individuals and families. The returns over  
19 the history of venture capital have  
20 fluctuated from year to year, but generally  
21 have been above 15 percent.

22 And these returns are what

1 encourage additional capital to come into our  
2 business, which allows us to continue to  
3 perpetuate the innovation process.

4           Venture capital companies  
5 represented 10 percent of the U.S. economy in  
6 2003. Over 10 million jobs were created,  
7 representing \$1.8 trillion of the U.S.  
8 economy. Between 1970 and 2003, over  
9 40 percent of the IPOs that happened were  
10 from venture capital backed companies. And  
11 these companies tend to spend twice as much  
12 in R&D than larger companies.

13           Over the last six years, we've seen  
14 a doubling of the amount of dollars that has  
15 been committed to the development of medical  
16 technologies. Very often what goes on in the  
17 information technology space in terms of the  
18 miniaturization of computers or chips and in  
19 material science ends up migrating into  
20 health care in terms of materials for  
21 catheters, to allow them to have  
22 steerability, or characteristics to allow

1    them to go into small places to do surgical  
2    procedures, and also material sciences in  
3    terms of drug-diluting technologies that  
4    allow you to place drugs in certain part of  
5    the body that have better dosing  
6    characteristics.

7                    Many of the innovations that are  
8    being used today in the practice of medicine  
9    have come out of venture capital. Over a  
10   million patients every year consume products  
11   that have come out of venture capital backed  
12   companies. And venture capital combats many  
13   of the leading causes of death, including  
14   heart disease, cancer and diabetes.

15                   Also, many venture capital backed  
16   science companies have developed the products  
17   that are currently under review by the FDA.

18                   In terms of the amount of money  
19   that gets spent in medical technology, the  
20   average medical technology company consumes  
21   \$30 million to \$60 million prior to a point  
22   where a venture capital firm gets liquid,

1 either through an IPO or an acquisition.

2           It's five times that in  
3 biotechnology. And this money is spent in  
4 terms of building operations, taking  
5 companies through the approval process and  
6 eventually building the sales and marketing  
7 team. And clearly the bulk of the dollars  
8 over the early history of these companies is  
9 spent on R&D.

10           If you look at the companies that  
11 really do the innovation in America today,  
12 virtually all of it comes from venture  
13 capital backed companies.

14           And if you look at the product  
15 offerings of large companies like Boston  
16 Scientific, Johnson & Johnson in the medical  
17 device area, St. Jude, Medtronic -- many,  
18 many of their products acquired a license  
19 from venture capital backed medical device  
20 companies. And very little innovation  
21 actually goes on in these three companies.

22           In terms of just a sampling of some

1 of the technologies that have been venture  
2 backed sponsored: Angioplasty back in the  
3 early '80s, cardiac defibrillators,  
4 technologies for minimally invasive breast  
5 surgery, painless glucose testing to  
6 encourage a number of patients to start  
7 monitoring their glucose more closely. So I  
8 won't go through all of these, but many, many  
9 of the technologies today that are helping  
10 patients came out of venture capital backed  
11 medical device companies.

12 In terms of looking forward, these  
13 are new areas that have consumed quite a bit  
14 of capital from our industry: Spinal nuclear  
15 replacements -- quite a bit in the spine  
16 area -- there continues to be quite bit in  
17 cardiology, neurology, in stroke -- also in  
18 the treatment of lower abdominal aortic  
19 aneurysms, taking surgical procedures and  
20 once again trying to make them minimally  
21 invasive or non-surgical.

22 So just quickly, Donna-Bea reviewed

1 the performance goals of MDUFMA, and clearly,  
2 the FDA has had a lot of success in reaching  
3 these. And we expect that they will continue  
4 in the future. But these goals haven't had a  
5 dramatic impact necessarily on speeding up  
6 the availability of novel technology or  
7 fostering more innovation. So what we'd like  
8 to do is see if there weren't ways to  
9 accelerate the commercialization of certain  
10 novel technologies.

11 We think novel technology  
12 submissions deserve particular attention, and  
13 it may be appropriate to focus for MDUFMA in  
14 setting performance goals or user fees to  
15 help speed up this process. We don't think  
16 performance goals should be met through  
17 increased issuance of non-significant  
18 equivalent decisions.

19 And we're hoping that review cycle  
20 goals, and shorter time frames for reviewing  
21 these technologies could result in more  
22 timely approvals.

1           Novel technology is a small but  
2 vital subset of the submissions, and they  
3 pose a significant challenge. Very often, a  
4 lower level staff may lack the clinical or  
5 regulatory expertise to fully appreciate the  
6 innovation, and may lack the experience in  
7 designing and executing appropriate clinical  
8 trials.

9           There are some policies that could  
10 improve the review of novel technology.  
11 These things include earlier participation by  
12 senior officials. Some of our companies have  
13 worked through ombudsmen very effectively.  
14 They seem to be very accessible and have been  
15 helpful in the process. Also, senior-level  
16 FDA reviewers tend to get the big picture a  
17 little earlier in the process.

18           We think maybe we can improve cycle  
19 time, the review of technology by involving  
20 outside experts to complement the staff here  
21 at the FDA. We want to encourage meetings  
22 earlier in the cycle process to set the

1 goals, and make sure that both the company  
2 and the FDA have clearer end points for the  
3 clinical trials, more flexibility in the  
4 advisory panel composition. And all of this  
5 we're hoping would result in improved cycle  
6 times, with the technology.

7           So what we're hoping to see in the  
8 future is, as technology becomes more complex  
9 and the FDA becomes more conservative, that  
10 there could be increased restrictions. And  
11 what we're hoping is that we can make the  
12 process predictable and less costly. Because  
13 right now, if you look over the last 20  
14 years, it took \$3 to \$4 million to bring  
15 angioplasty to the market. More recently in  
16 2000, it took \$400 million to get regular  
17 stents into the marketplace.

18           So these timing delays are very  
19 costly, certainly have the impact on returns  
20 in venture capital in our ability to retract  
21 money to bring more novel technologies to  
22 market. So the FDA could help commercialize

1 these technologies by helping with more  
2 timely approval processes, and all of this  
3 will help drive down health care  
4 expenditures.

5           So we'd just like to see a approval  
6 pathway for innovative technologies. We'd  
7 like to see the FDA meet 510(k) performance  
8 goals with more timely reviews instead of  
9 increased issuance of NSE decisions, and  
10 earlier resolution of issues and greater  
11 collaborations which would shorten review  
12 cycles and approval time frames.

13           Thanks.

14           MR. BARNETT: Thank you,  
15 Mr. Douglass. Does anyone in the panel have  
16 questions for Mr. Douglass? Yes.

17           DR. TILLMAN: I want to ask about  
18 the --

19           MR. BARNETT: Why don't you use the  
20 mic.

21           DR. TILLMAN: I'd like to ask about  
22 the bullet under "Policies that would improve

1 the review of novel technologies." One of  
2 the bullets you have is flexibility in  
3 advisory panel composition. Can you talk a  
4 little bit about what that means?

5 MR. KIDMAN: Sure.

6 MR. BARNETT: Let's use the mic.

7 MR. KIDMAN: I'm Paul Kidman here  
8 with the Association. I think part of the  
9 interest was seeing whether the ability to  
10 add to the composition of standing committees  
11 on the basis of -- if there's a belief that  
12 (inaudible) technologies were not even  
13 looking for a -- getting a forum -- whether  
14 it is outside consultancies or general  
15 experts, a team brought to it, consistent  
16 with the existing standards for investigating  
17 composition and consultation.

18 There are different options that  
19 we'd like to explore and see if there are  
20 ones that would be consistent with current  
21 law and current regs with the other  
22 alternatives that would be possible.

1 MR. BARNETT: Does that answer it?  
2 Anyone else have a question? Okay. Thank  
3 you then, Mr. Douglass. And our next speaker  
4 is Jori Frahler from the Medical Device  
5 Manufacturers Association.

6 MS. FRAHLER: Good morning. My  
7 name is Jori Frahler, and I'm here on behalf  
8 of innovative and entrepreneurial companies  
9 that the Medical Device Manufacturers  
10 Association represent.

11 I would like to thank the FDA for  
12 the opportunity to address two performance  
13 goals that were included in the Medical  
14 Device User Fee and Modernization Act of  
15 2002. When MDUFMA was enacted in 2002, the  
16 goal of the program was to provide CDRH and  
17 CBER with additional resources through  
18 Congressional appropriations and industry  
19 user fees to ensure that patients have timely  
20 access to safe and effective medical  
21 technologies.

22 At that time, the device industry

1 was told that review times would improve on  
2 average by 25 percent. Unfortunately, while  
3 additional resources have been provided  
4 through appropriations and user fees, real  
5 enhanced performance has for the most part  
6 not been achieved.

7 In fact, a recent (inaudible)  
8 report prepared for the FDA found that only  
9 70 percent of responding device manufacturers  
10 perceived that MDUFMA goals had not resulted  
11 in meaningful improvements in either the  
12 predictability or timeliness for device  
13 review.

14 Many expressed that review times  
15 have at best remained about the same compared  
16 to pre-MDUFMA experiences. In some areas,  
17 review times have actually gotten worse under  
18 MDUFMA. For example, in fiscal year 2000,  
19 47 percent of original PMAs were issued a  
20 final decision within 180 FDAs.

21 And even with additional  
22 Congressional appropriations and well over

1 \$100 million in industry user fees, achieving  
2 the 50 percent goal may not be possible. And  
3 this is disappointing.

4 The news for the 510(k) goal is  
5 better. Prior to MDUFMA, in fiscal year  
6 2000, 80 percent of the 510(k)s had a final  
7 decision within 90 FDA days. During the  
8 first two years of MDUFMA, the percentages  
9 were 77 and 76 respectively.

10 In fiscal year 2004, FDA reached a  
11 final decision on 83 percent of the 510(k)s.  
12 In fiscal year 2005, the percentage of  
13 510(k)s reviewed in 90 FDA days will be  
14 between 87 and 93 percent.

15 Based on the experiences of our  
16 members and the entire medical technology  
17 industry, it is clear that MDUFMA needed some  
18 modifications in order to achieve the intent  
19 of the program, which was to provide patients  
20 and physicians with timely access to  
21 receiving effective products.

22 We look forward to working with FDA

1 and Congress to develop a program that truly  
2 enhances the review process to achieve the  
3 objective stated about -- as MDMA stated  
4 during the November 2005 MDUFMA stakeholder  
5 meeting, MDUFMA too must include reasonable  
6 and rational fees coupled with real enhanced  
7 performance in order to generate support in  
8 the medical technology industry.

9 And we're hopeful that this can  
10 occur, and that the result would be a win for  
11 patients and innovation. Thank you.

12 MR. BARNETT: Thank you. Any of  
13 the panelists have a question? If not, thank  
14 you. And our next speaker is Janet Trunzo  
15 from AdvaMed.

16 MS. TRUNZO: Good morning. I'm  
17 Janet Trunzo with AdvaMed, and I'd like to  
18 thank FDA for the opportunity to speak today.  
19 AdvaMed is a large trade association for  
20 medical devices and technology companies.

21 In AdvaMed, our members produce  
22 nearly 90 percent of the health care

1 technology purchased annually in the U.S.,  
2 and nearly 50 percent of that purchase  
3 worldwide. Our members range from the  
4 smallest to the largest health medical  
5 innovators and companies.

6 In fact, over 70 percent of our  
7 members are of small company composition.  
8 And we always keep in the front of our minds  
9 that improving patient care is our highest  
10 priority. So I'm pleased to be here to  
11 discuss FDA's performance under MDUFMA. This  
12 is a topic near and dear to my heart because  
13 I was involved in the 2002 negotiations. I  
14 was involved in establishing and working with  
15 FDA to come to these goals.

16 So I have a real personal interest  
17 in this. So I would like to kind of give you  
18 where I'm coming from on this. We all agree  
19 here today that MDUFMA was designed to  
20 provide FDA with the resources it needs to  
21 review the applications that it receives in a  
22 timely manner. We fully recognize that user

1 fees were designed to affect the timeliness  
2 of the reviews, but not the outcome of the  
3 review.

4           However, the premise of the user  
5 fee program is that with additional  
6 resources, devices that demonstrate a  
7 reasonably assurance of safety and  
8 effectiveness will get to the market more  
9 quickly where they can benefit the patients  
10 who actually need them.

11           Today's meeting, of course, as was  
12 stated earlier, is held in accordance with  
13 the statutory provision of MDUFMA to focus on  
14 these two goals.

15           And we have heard where FDA is on  
16 the goals, and we have heard what FDA  
17 believes the future of these two goals are.  
18 However, the bottom line for us, for AdvaMed,  
19 is that we expect FDA to meet all the goals  
20 now that it has the resources to do so.

21           Indeed, senior administration  
22 officials as well as senior FDA officials

1 have since the passage of MDUFMA repeatedly  
2 committed to meeting these performance goals.  
3 In particular, then-OMB Director Josh Bolten  
4 stated in a letter to Congress that FDA would  
5 meet all the goals in MDUFMA if full  
6 appropriations were received in fiscal year  
7 2005. And that did in fact occur.

8 FDA has reiterated this commitment  
9 multiple times; for example, in testifying  
10 before the Agriculture Subcommittee as well  
11 as in written answers to questions posed by  
12 that subcommittee. So accordingly, we expect  
13 FDA to meet the goals.

14 As with much of MDUFMA, however,  
15 this story is a mixture of good news and bad  
16 news. The good news is that FDA is meeting  
17 the goal reviewing 80 percent of the 510(k)  
18 reviews within 90 days.

19 This is consistent when FDA's  
20 historic high level of attention to 510(k)  
21 reviews. And we commend the Agency for  
22 keeping its focus on 510(k) applications in

1 such a way that produced this high degree of  
2 efficiency.

3           However, the bad news, as we heard  
4 earlier, is that FDA is falling well short of  
5 meeting the second goal of reviewing  
6 50 percent of the PMA applications in 180  
7 days. In fact, it has decreased since 2002,  
8 where it was around 49 percent.

9           And when we put that goal in place,  
10 we assumed that it was a reasonable goal,  
11 because at the time, FDA was meeting the PMA  
12 goal of 49 percent at the time.

13           We believe that FDA needs to bring  
14 greater focus and attention on the management  
15 of the PMA process, because this is where  
16 most of the significant new products come  
17 from. American patients need these products.  
18 The medical device companies have worked hard  
19 to develop the necessary data to justify  
20 their marketing under the terms of the law.

21           We have made improving the PMA  
22 review process a major focus of MDUFMA

1 reauthorization. But at the same time, we  
2 also call upon FDA to take steps now to focus  
3 its management process on the review of  
4 applications so that the FDA can meet the PMA  
5 review goal established in 2002. We owe that  
6 to the American patients.

7 I thank you very much for the  
8 opportunity to speak today.

9 MR. BARNETT: Thank you,  
10 Ms. Trunzo, before you leave just any of the  
11 panelists have a question? No.

12 MS. TRUNZO: None?

13 MR. BARNETT: Okay. Our final  
14 speaker is Diane Zuckerman, from the National  
15 Research Center for Women & Families.

16 MS. ZUCKERMAN: I'm Dr. Diane  
17 Zuckerman. I'm president of the National  
18 Research Center for Women & Families. We're  
19 a non-profit organization dedicated to  
20 improving the health and safety of women,  
21 children and families. And we spend a lot of  
22 time looking at FDA issues, so I'm very happy

1 to be here today, and I appreciate the  
2 opportunity.

3 We're also a member of the Patient  
4 and Consumer Coalition, which is a coalition  
5 of many patient and consumer groups,  
6 obviously, well known groups such as the  
7 Consumer Union and AARP, groups that aren't  
8 as well known to you such as the National  
9 Women's Health Network, but a large coalition  
10 and flexible coalition.

11 I'm not speaking on behalf of them,  
12 but wanted to say that there are many  
13 consumer groups that are very interested in  
14 this meeting today and they were not all able  
15 to come. They were not able to come, partly  
16 because of the location and the timing, and  
17 also because of the narrowness of the focus,  
18 and weren't sure that it was appropriate for  
19 them to be here.

20 But we wanted to be here to talk  
21 about the issues that we all share, the  
22 patient groups, the consumer groups and all

1 of us in this room, because we know that we  
2 all are dedicated to making sure that there  
3 are medical devices on the market as soon as  
4 possible, but that those products are safe as  
5 well as effective.

6           So in coming here today, I really  
7 wanted to talk about those shared goals, and  
8 the fact that there are a lot of  
9 patient/consumer groups obviously that care  
10 very much about innovative products, and  
11 getting them to the market. But we also care  
12 very much about making sure that those  
13 products are safe. And I want to spend a  
14 couple of minutes talking about the 510(k)  
15 process, because obviously, FDA has done a  
16 great job in getting these products to the  
17 market quickly.

18           But we are also very concerned,  
19 because they are generally not as innovative  
20 and not as crucial, to make sure that the  
21 process really is looking at everything that  
22 needs to be looked at in terms of safety.

1           And we think that the Bausch and  
2 Lomb example is a good one, not because we  
3 know that patients had been harmed with eye  
4 infections because presumably because of  
5 renewed (inaudible), but because the FDA's  
6 inspection report which is available online  
7 shows a long series of problems with that  
8 product, not just looking at sterility, which  
9 is certainly something that you would care  
10 about if you wear contact lenses as I do, but  
11 also because of a product that had certain  
12 instructions such as whether -- the lens  
13 solution needed to be rubbed on a contact lens,  
14 whether it needed to be rinsed off the  
15 contact lens, really basic stuff for anybody  
16 who wears contact lenses that according to  
17 the inspection report had not been verified  
18 with safety data.

19           So it was giving instructions that  
20 were not based on the data. And for those  
21 kinds of issues, regardless of whether those  
22 were the causes of the infections or not, we

1 think that is instructive, because the 510(k)  
2 process is used so frequently. And so we  
3 need to make sure that these products that  
4 are using this process have been adequately  
5 studied to make sure that the products really  
6 are safe.

7           The PMA process obviously is a  
8 different situation. We think that the FDA  
9 is trying very hard to make sure that that  
10 process is appropriate. And one of the  
11 things that's striking when you look at  
12 averages is how a few products that perhaps  
13 have a very long process can throw off all  
14 your averages. And so as consumer and  
15 patient groups, we want to focus on how to  
16 make sure that the FDA can continue to  
17 scrutinize certain products that they're  
18 worried about without throwing off all of  
19 their averages. And we think that's  
20 something that's worth considering as this  
21 legislation is reviewed in the future.

22           Also wanted to just mention that we

1 don't think that the problem is the lack of  
2 expertise on the part of the FDA scientific  
3 staff. We are very impressed with the  
4 expertise on the FDA scientific staff. So  
5 our concern is more the pressures on the  
6 scientific staff to move quickly, and to  
7 sometimes move more quickly than members of  
8 the scientific staff feel comfortable about.

9 I just very briefly want to mention  
10 that in the last couple of weeks, I spent a  
11 fair amount of time with Dr. Frances Kelsey,  
12 an FDA scientist, formerly -- a retired  
13 scientist who was of course the scientist who  
14 reviewed thalidomide in the early 1960s, at a  
15 time when FDA apparently had eight full-time  
16 reviewers.

17 And she was the person responsible  
18 for making sure that thalidomide did not get  
19 approved in United States at a time when it  
20 was already widely used in Europe. And  
21 meeting with her, she's now in her nineties,  
22 was a very moving experience, because at the

1 time, she was under a lot of pressure to get  
2 things moving.

3 She had worked at the FDA for a  
4 month when she was asked to review  
5 thalidomide. She was given that review as a  
6 simple product to review for her first  
7 review, because it was assumed that it was  
8 safe since it was being used throughout  
9 Europe.

10 And because she had concerns about  
11 it and felt that the research wasn't adequate  
12 and kept asking for more research, the  
13 company did pressure the FDA to get rid of  
14 her, or at least ignore what she was saying.

15 But thousands of children did not  
16 have birth defects in this country, very  
17 serious birth defects -- of not having fully  
18 developed arms and legs -- because she did  
19 her job. So I think that's a really good  
20 reminder to all of us of how important the  
21 work of the FDA is.

22 We really thank you for that.

1           So in summary, I just want to say  
2           that we understand that timing delays are  
3           costly, but we also think rushing approval is  
4           costly. Both things are costly. And I think  
5           that Bausch and Lomb is a really good example  
6           of how a company which had an excellent  
7           reputation is being hurt now by, I would say,  
8           their own sloppiness, but also a process that  
9           perhaps moved too quickly in that particular  
10          case.

11                 We're also not particularly  
12          concerned with adding expertise to the  
13          standing committees, the FDA advisory  
14          committees. We think that the FDA does a  
15          good job of adding expertise when it's  
16          needed. And we're actually concerned to make  
17          sure that that expertise does not include  
18          people with conflicts of interests with the  
19          products that they're reviewing.

20                 So just to finish up, just to say  
21          that we are sympathetic to the FDA's desire  
22          to meet its goals, its stretch goals, but we

1 think that adding more resources for the PMAs  
2 particularly would be a very bad idea. And  
3 we also would ask the FDA to look more  
4 carefully at the 510(k) process to make sure  
5 that it is not moving too quickly in some  
6 cases, and as a result, patients can be  
7 harmed.

8 Thank you.

9 MR. BARNETT: Thank you,  
10 Dr. Zuckerman.

11 Any questions for Dr. Zuckerman  
12 from the panel? Let me ask if there's anyone  
13 else in the room that wants to speak. Can I  
14 see any hands? Going once, going twice.

15 SPEAKER: Highly energized crowd.

16 MR. BARNETT: If that's the case,  
17 let me give you a couple of final  
18 housekeeping remarks, and then I'm going to  
19 ask Linda to close the meeting.

20 First of all, if you have  
21 additional comments or something occurs to  
22 you, you still have 30 more days to submit

1     them to the docket before we submit our  
2     letter to the Congress. You will find the  
3     docket number and the address and how to do  
4     that in the handout packet that you should  
5     have received today.

6             And the second housekeeping point  
7     is that transcripts of this meeting are going  
8     to be available on July 1st. And you will  
9     find instructions for getting a transcript in  
10    the handout packet.

11            And with that, I'll ask Linda to  
12    make a final comment or two.

13            MS. KAHAN: Thank you. I think we  
14    got a variety of perspectives from the  
15    audience, and we appreciate that.

16            What are our next steps are going  
17    to be? Some of them, of course, are obvious.  
18    We're going to read the transcript of  
19    everything that we've heard so that we can  
20    look at that again and hear what you had to  
21    say.

22            And as Mark said, you do have

1 additional time to send comments into the  
2 docket.

3           And we'll look at what comes into  
4 the docket and will be preparing the report  
5 that we need to do for Congress after we make  
6 a final decision.

7           The other thing that we're going to  
8 do was alluded to by Donna-Bea, and I think  
9 by Janet as well, which is that we are  
10 actively working with people who are  
11 concerned to try to get together a package of  
12 recommendations that would be useful for  
13 possible reauthorization of this program,  
14 that would address some of the concerns that  
15 everybody has raised here.

16           And in relationship to that, let me  
17 give you an advance invitation to a meeting  
18 we're planning for October. I think the  
19 tentative date is October 26th. I don't know  
20 if that's been finalized, but it will be in  
21 October, and that will be the Annual  
22 Stakeholders Meeting for 2006.

1           And at that meeting, we will  
2   hopefully have recommendations for moving  
3   forward with the program that we will want  
4   your feedback on. And that certainly would  
5   be the appropriate time, Dr. Zuckerman, for  
6   all of those other groups who want a broader  
7   picture to attend as well.

8           We hope that that will be a useful  
9   forum. It has been in the past for us to  
10   move forward. And that's what we hope for.  
11   We hope that we'll be able to continue to  
12   hear from you.

13           We hope that we'll be able to  
14   continue to implement the program, to grow  
15   some of the efficiencies that Janet and Jori  
16   were talking about, and to keep going so that  
17   when the time comes for the program to be  
18   renewed, we'll be able to agree with all of  
19   our stakeholders that we can put something in  
20   place that will benefit the patients and the  
21   doctors you just described.

22           So again, thank you very much for

1 coming.

2 MR. BARNETT: Thank you all for  
3 coming.

4 We'll now close.

5 (Whereupon, at approximately  
6 10:11 a.m., the PROCEEDINGS were  
7 adjourned.)

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## CERTIFICATION OF TRANSCRIPT

I certify that the attached transcribed meeting, in the matter of the Food and Drug Administration, on May 22, 2006 was held as herein appears and that this is the original transcript.

I, the undersigned, do certify that this is a true, accurate and complete transcript prepared from the digital recording taken by Christopher Mazzochi, of Beta Court Reporting, on the aforementioned date, and that I have verified the accuracy of the transcript by comparing the typewritten transcript against the verbal recording.

Transcriber/Proofreader:

Andy White

Date:

6/5/06