

5/16/06

**BARNETT INTRO FOR MDUFMA MEETING**

**MAY 22, 2006**

**I'D LIKE TO WELCOME YOU TO THIS PUBLIC MEETING TO DISCUSS A SPECIFIC ASPECT OF THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT, OR MDUFMA AS WE ALL KNOW IT.**

**TODAY'S MEETING WILL FOCUS ON TWO OF THE REVIEW PERFORMANCE GOALS THAT FDA AGREED TO CONSIDER FOR FY 2007 WHEN MDUFMA'S PERFORMANCE GOALS WERE DRAFTED BACK IN 2002. WHEN THE FDA, STAKEHOLDERS, AND CONGRESS DRAFTED MDUFMA'S PERFORMANCE GOALS, EVERYONE AGREED THESE TWO GOALS WERE POTENTIALLY VERY CHALLENGING. AND SO RATHER THAN COMMIT FDA TO GOALS THAT IT MIGHT NOT BE ABLE TO MAKE, IT WAS AGREED THAT FDA WOULD REVIEW ITS PROGRESS~AND WOULD HOLD A PUBLIC MEETING FOLLOWING THE CLOSE OF FY 2005 TO HELP DECIDE WHETHER IT WOULD BE APPROPRIATE TO IMPLEMENT THESE GOALS FOR FY 2007.**

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**AND OF COURSE THAT'S WHY WE'RE HERE TODAY.**

**THE FIRST OF THOSE TWO GOALS IS THAT 50 PERCENT OF THE PREMARKET APPROVAL APPLICATIONS RECEIVED IN FISCAL YEAR 2007 WILL HAVE AN FDA DECISION IN 180 DAYS.**

**AND THE SECOND GOAL IS THAT 80 PERCENT OF PREMARKET NOTIFICATIONS, OR 510(K)'S, WILL HAVE AN FDA DECISION IN 90 DAYS.**

**IF FDA DECIDES THAT ONE OR BOTH OF THESE GOALS ARE NOT APPROPRIATE, THEN WE MUST SUBMIT A REPORT TO CONGRESS PROVIDING OUR RATIONALE FOR NOT IMPLEMENTING THE GOAL.**

**WHAT WE NEED FROM YOU TODAY ARE YOUR THOUGHTS ABOUT THE FEASIBILITY AND DESIRABILITY OF IMPLEMENTING THESE TWO PERFORMANCE GOALS IN FISCAL YEAR 2007.**

**IN ORDER TO HEAR YOU, WE'VE ASSEMBLED A PANEL OF FDA MDUFMA EXPERTS. LET ME INTRODUCE THEM.**

**LINDA KAHAN IS DEPUTY DIRECTOR OF FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.**

**DR. DONNA BEA TILLMAN IS DIRECTOR OF THE CENTER'S OFFICE OF DEVICE EVALUATION.**

**AND DIANE MALONEY IS ASSOCIATE DIRECTOR FOR POLICY IN FDA'S CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.**

**NOW LET ME TELL YOU ABOUT THE FORMAT FOR TODAY'S MEETING. FIRST I'M GOING TO ASK LINDA TO FILL US IN ON THE HISTORY OF THESE TWO PERFORMANCE GOALS AND WHAT THE FRAMERS OF THE MDUFMA LEGISLATION HAD IN MIND WHEN THEY DEVELOPED THEM.**

**THEN DONNA BEA TILLMAN IS GOING TO DISCUSS WHAT WE'VE DONE TO MEET THE VARIOUS MDUFMA GOALS FOR THE PREMARKET EVALUATION AND APPROVAL OF MEDICAL DEVICES, AND OUR TRACK RECORD IN MEETING THOSE GOALS.**

**DONNA BEA' WILL THEN GO ON TO EXPLAIN FDA' S POSITION ON WHETHER OR NOT TO IMPLEMENT THESE TWO PARTICULAR PERFORMANCE GOALS IN FISCAL YEAR 2007, AND SHE'LL PROVIDE THE RATIONALE FOR THAT POSITION.**

**ONCE THAT HAPPENS, WE'LL OPEN THE FLOOR AND HEAR YOUR COMMENTS ON WHETHER OR NOT WE SHOULD IMPLEMENT THESE TWO GOALS IN FISCAL YEAR 2007. 4 PEOPLE HAS SIGNED UP IN ADVANCE TO SPEAK, AND WE'LL HEAR FROM THEM FIRST. THEN WE'LL TAKE COMMENTS FROM ANYONE ELSE WHO'D LIKE TO SPEAK. THE MEETING IS BEING RECORDED BY A STENOGRAPHER, SO WE'LL HAVE A PERMANENT RECORD OF WHAT YOU SAY HERE TODAY.**

**BEFORE WE BEGIN, LET ME GIVE YOU A COUPLE OF SIMPLE GROUND RULES FOR WHEN YOU PRESENT YOUR COMMENTS.**

**FIRST, BECAUSE OF THE VERY SPECIFIC NATURE OF THIS MEETING, WE WANT COMMENTS ONLY ON THE TWO PERFORMANCE GOALS UNDER CONSIDERATION.**

**THIS IS NOT A MEETING ABOUT FDA'S MEDICAL DEVICE PROGRAM IN GENERAL. IN FACT IT'S NOT EVEN ABOUT MDUFMA IN GENERAL. IT'S ABOUT TWO SPECIFIC MDUFMA PERFORMANCE GOALS RELATING TO PREMARKET APPROVALS AND PREMARKET NOTIFICATIONS. AS WE EXPLAINED IN THE FEDERAL REGISTER NOTICE ANNOUNCING THIS MEETING, IT'S IN THAT HIGHLY FOCUSED AREA WHERE WE'RE ASKING FOR YOUR THOUGHTS.**

**THE SECOND SIMPLE GROUND RULE IS THAT PRESENTATIONS FROM THE FLOOR SHOULD LAST NO LONGER THAN 10 MINUTES EACH. I'LL WATCH THE TIME, AND I'LL GIVE YOU A SIGNAL WHEN YOU HAVE TWO MINUTES REMAINING, AND THEN ASK YOU TO WIND IT UP AT THE 10-MINUTE MARK.**

**NOW THAT WE'VE TALKED ABOUT WHY WE'RE HERE, WHAT WE WANT TO ACCOMPLISH, AND HOW WE'LL GO ABOUT IT, LET ME ASK LINDA KAHAN FOR SOME OPENING COMMENTS.**

**[CALL ON LINDA]**

**CLOSE**

**BEFORE WE LEAVE, LET ME THANK YOU FOR YOUR PARTICIPATION TODAY AND REMIND YOU THAT IF PERFORMANCE GOALS, YOU STILL HAVE 30 MORE DAYS TO SUBMIT THEM TO THE DOCKET/ YOU'LL FIND THE DOCKET NUMBER AND ADDRESS IN THE HANDOUT PACKET YOU RECEIVED TODAY.**

**ALSO, TRANSCRIPTS OF THIS MEETING WILL BE AVAILABLE BY JULY 1. YOU'LL FIND INSTRUCTIONS FOR GETTING A TRANSCRIPT IN YOUR HANDOUT PACKAGE.**

***[CALL ON LINDA FOR CLOSING COMMENTS.]***