

FDA Advisory Committee Meeting Email (ctgtac roster), June 25, 2009 - Laviv

From: Dapolito, Gail
Sent: Thursday, June 25, 2009 3:38 PM
To: Thomas, John; Tull, Lori
Subject: FW: FDA Advisory Committee meeting

Attachments: ctgtac roster.doc

FYI

From: Dapolito, Gail
Sent: Thursday, June 25, 2009 3:37 PM
To: 'jnovak@cbrintl.com'
Subject: FDA Advisory Committee meeting

Dear Jeanne,

It was a pleasure speaking with you today about the upcoming Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) meeting.

The CTGTAC will meet on October 9. As soon as we get a venue, I will notify you.

Here is the link to the Guidance: Preparation and Public Availability of Information Given to Advisory Committee Member.

As I mentioned, the briefing documents (Isolagen's and FDA's) will be posted on the FDA website 48 hours prior to the meeting.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125650.pdf>

If Isolagen's document is fully releasable, it should be sent to me by Sept. 9. If not fully releasable the due date is August 11.

Please see the guidance for more details.

I will need approximately 35 copies of the briefing document. We will accept hard copies or CDs. If sending CDs, please also include 1 hard copy.

The agenda, questions, etc are a work in progress and I will follow-up as they are firmed up. The usual outline for the agenda is for the sponsor and FDA to have 60-90 minutes for presentation.

If you would like to provide hard copies of slides to the Committee members (this is usually done as a courtesy as it helps the members in the discussion); please bring approx. 35 copies of slides to the meeting. It would be greatly appreciated if you would also share slides with FDA staff at least a week or so before the meeting.

I also attached the current [CTGTAC roster](#). There are vacancies we are trying to fill before the meeting. I will notify you of any changes/new members to the roster.

Related Information

- [CTGTAC roster, June 25, 2009 - Laviv](#) [ARCHIVED]

Page Last Updated: 07/19/2011