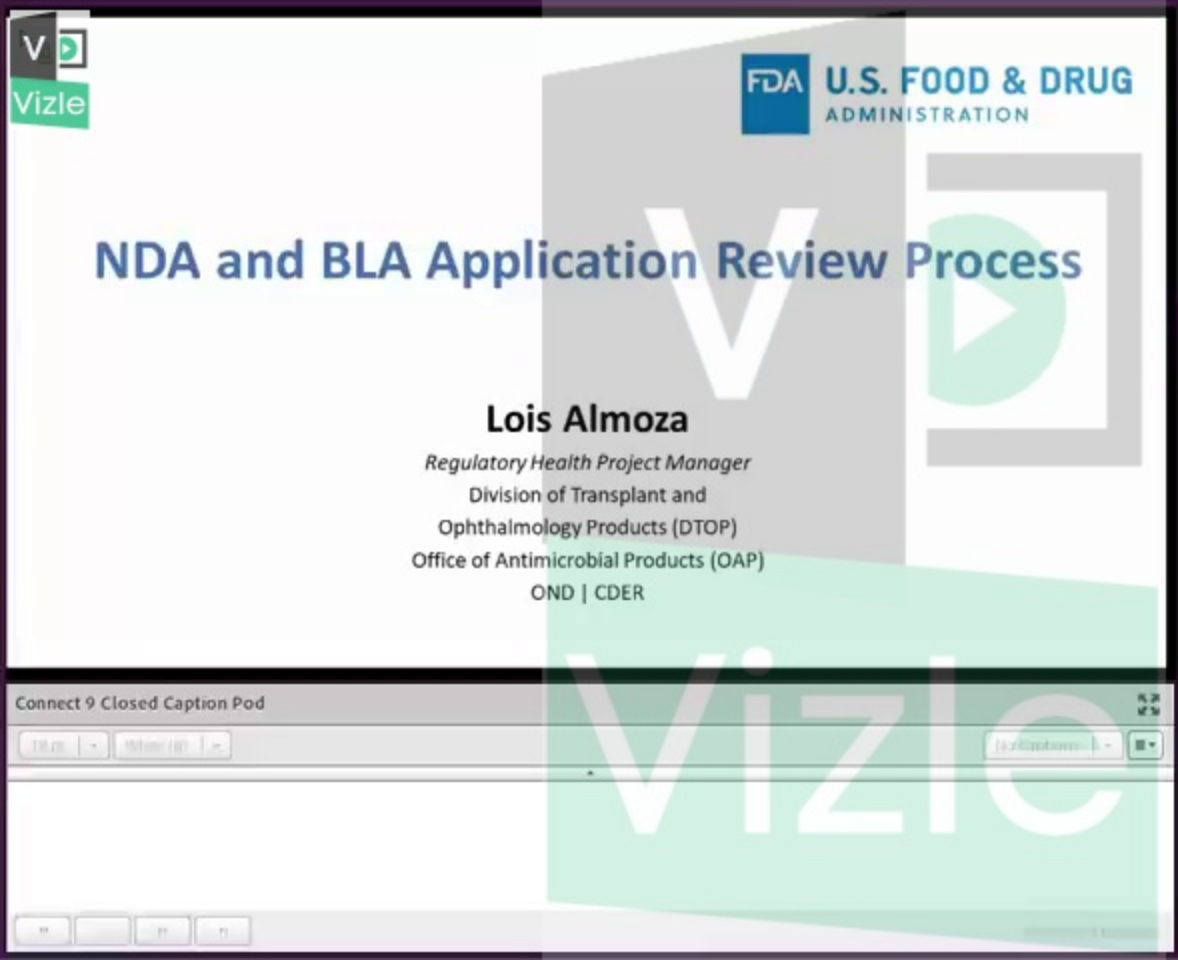
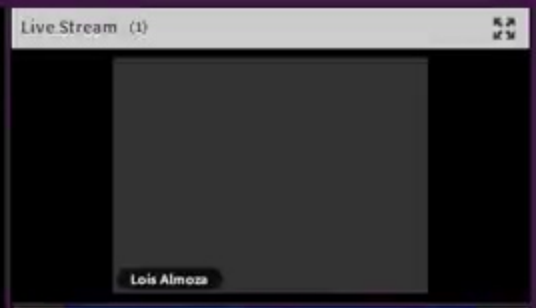
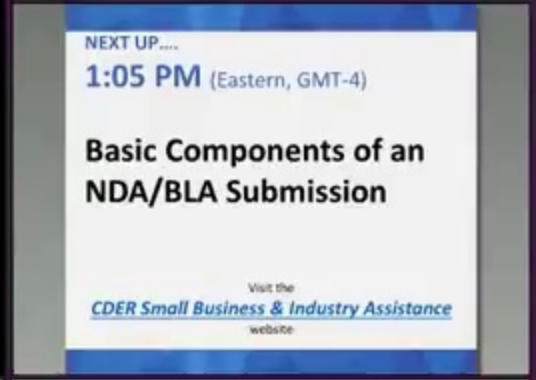

FDA U.S. FOOD & DRUG ADMINISTRATION
NDA and BLA Application Review Process
Lois Almoza
Regulatory Health Project Manager
Division of Transplant and
Ophthalmology Products (DTOP)
Office of Antimicrobial Products (OAP)
OND | CDER


Live Stream (1)
Lois Almoza


NEXT UP....
1:05 PM (Eastern, GMT-4)
Basic Components of an NDA/BLA Submission
Visit the
CDER Small Business & Industry Assistance
website

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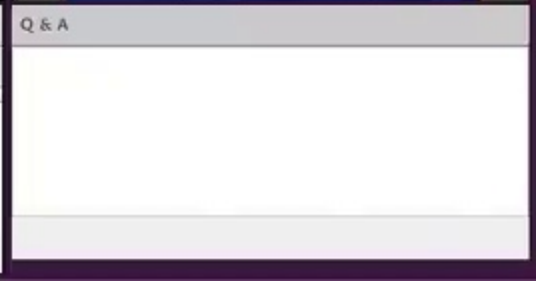
Q & A

Initial Review
RPM Responsibilities

Regulatory Project Manager (RPM) receives initial NDA submission

- Prescription Drug User Fee Act (PDUFA) time clock begins when application is received
  - Use the received date when calculating dates, NOT the letter date.
  - Acknowledge application receipt in writing by Day 14
- Ensure conformance to regulatory requirements
  - Ensure correct across internal tracking systems
  - Administratively complete and compliant
  - Confirm proposed proprietary name was submitted separately where applicable
- Conduct Physician Labeling Rule (PLR) format review of the prescribing information
- Begin RPM filing review

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Conference Resources

(Slides, Agenda, Recordings, Etc.)

NDA and BLA Application Process: A Brief Overview

Evaluate Speaker

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We want to make sure that it is tracked appropriately.

We want to make sure that it is administratively complete and compliant during this early time of looking at the application.

And if you have a propose proprietary name for review, we are making sure that that was also coded separately.

Live

Q & A

Message from *Moderator: Jeff Kelly*

If you have any questions for our presenter(s), please place them in this pod.

Program Timelines

What's Different for NME Program review?	What's the Same for NME Program reviews?
6/10 mo clocks begin at 60 day filing date	User fees, other than usual yearly increases
Agreement on complete application at pre-submission meeting	60-day filing decision
Late submissions w/in 30 days of application receipt, if agreed upon at the pre-sub meeting	Refuse To File and Standard/Priority review criteria
Mid-cycle communication	74-day letters
Late-cycle meeting, including *FDA* meeting package	PMRs/PMCs + labeling discussions

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NDA and BLA Application Process: A Brief Overview

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We will not be dedicating our resources to trans, translating your application.

I know that's a scary term for everybody.

We have the criteria for the refusal file.

Live

Q & A

Message from *Moderator: Jeff Kelly*

If you have any questions for our presenter(s), please place them in this pod.

Conduct Review- Mid-Cycle (Program Applications Only)

Internal Mid-Cycle Communication Planning:

- Determine what to convey to applicant with regard to identified key issues/deficiencies and the need for additional information
- Date or proposed date for the Late Cycle Meeting (LCM) and other projected milestone dates for the remainder of the review cycle
- Advisory Committee update (if applicable)
- Postmarketing Requirements (PMR)/Commitments (PMC) and Risk Evaluation and Mitigation Strategies (REMS) issues
- Timeline for review activities associated with a scheduling recommendation under the Controlled Substances Act (if applicable).
- Determine who will convey the deficiencies/information, and the order in which the deficiencies/information will be conveyed
- Determine who will participate in the Mid-Cycle Communication Meeting

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If there is an advisory committee we will update you on that.

And then again, who will put it is up eight in the meeting.

Who is going to be available.

Live

Q & A

Message from *Moderator: Jeff Kelly*

If you have any questions for our presenter(s), please place them in this pod.

Taking an Action - (Tentative Approval)

- If the action is to tentatively approve the application, the RPM drafts a Tentative Approval Letter and circulates it for editing by the review team (including the signatory authority)
  - Due to Patent and/or Exclusivity
  - Due to Orphan Exclusivity
  - Due to a 30-month Stay/Patent Infringement Complaint
- A drug product that is granted tentative approval is not an approved drug and cannot be marketed until an approval letter is issued by the FDA.
- To obtain final approval of this application, submit an amendment two or six months prior to the: (1) expiration of the patent(s) and/or exclusivity protection or (2) date you believe that your NDA will be eligible for final approval, as appropriate.
- 21 CFR 314.105

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You resubmit your application after you talk to Wes.

You may feel that our deficiencies were very clear and you agree with them.

But anyway, when you are ready to resubmit, you resubmit your application and we will see if it is class 1 our class 2 which means it could take from two to six months.

Live

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Q & A

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