

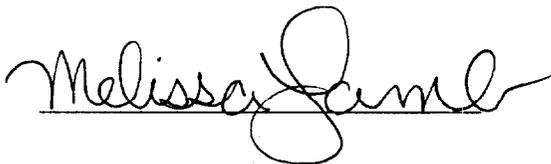
M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
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Date: January 24, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Presentation Regarding Human Generic Drugs to Docket
90S-0308

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: 180-day exclusivity
Presented for: FDLI/FDA 43rd Educational Conference
Date Presented: 12/17/99
Presented by: Douglas L. Sporn
Number of Pages: 10



Attachment

90S-0308

M685

FDLI/FDA
43rd Educational Conference

180-Day Exclusivity

*Douglas L. Sporn, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration*

December 17, 1999

180-Day Generic Drug Exclusivity

- August 6, 1999 - Proposed Rule
Published
- November 4, 1999 - Comment Period
Closed
- Number of Commentors - 18

Why a Proposal?

- Previous regulation was successfully challenged in the courts
 - *Mova Pharmaceutical Corp v. Shalala, 1998*
 - *Granutec, Inc. v. Shalala, 1998*

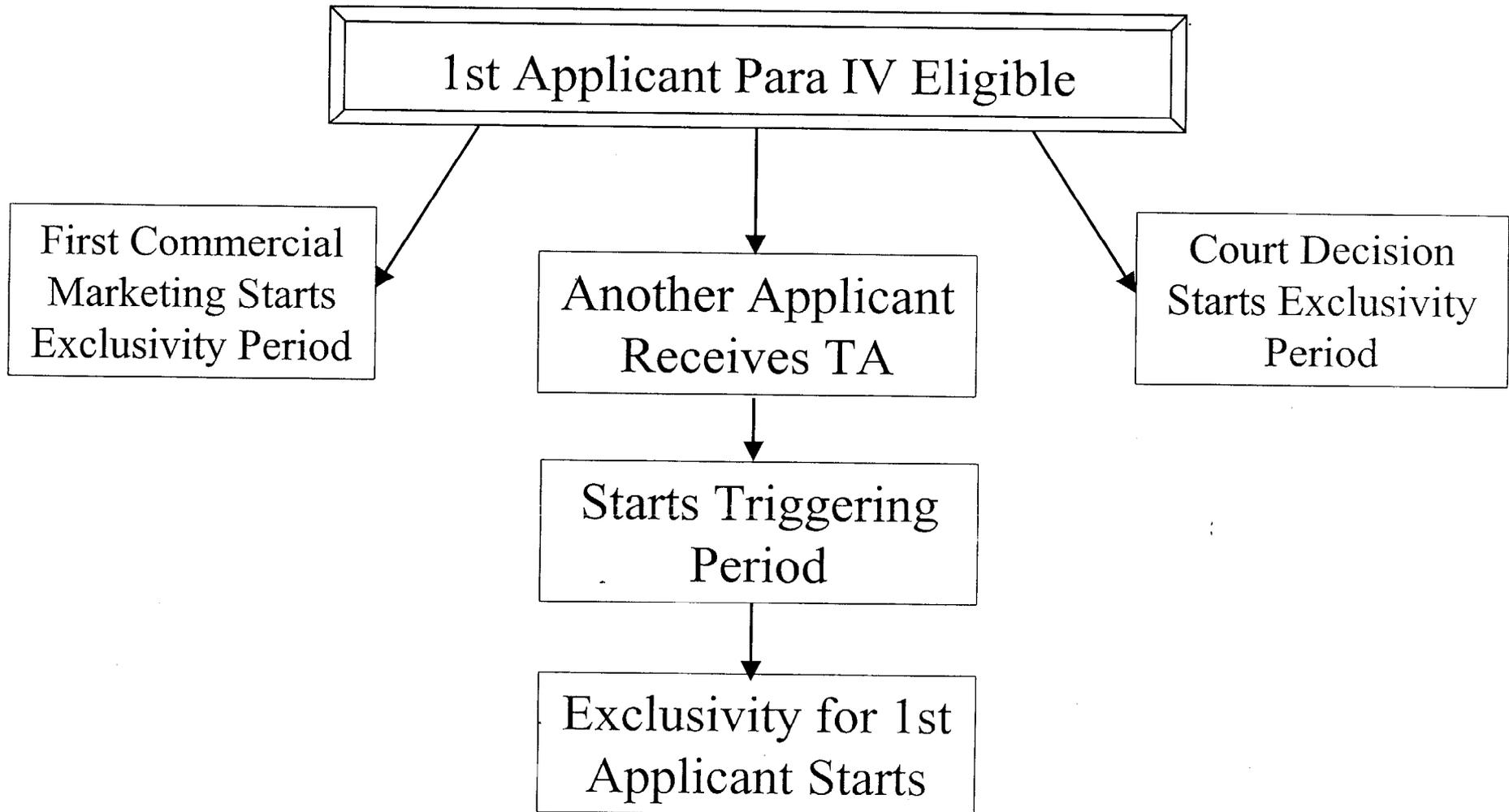
Who is Eligible?

- Only the First Applicant with Paragraph IV Certification to any Patent
- Substantially Complete Application
(Including meeting bioequivalence standards for approval)
- Filed

When Does Exclusivity Begin?

- "A" Court Decision
- First Commercial Marketing
- After the Triggering Period

What Starts the 180-day Exclusivity Period?



Triggering Period

- 180 Days - From Tentative Approval of Subsequent Applicant
- 60 Days - First Applicant has Final Approval Not Sued or Case was Settled or Dismissed

Triggering Period

- Exceptions - Triggering Period Would Not Start Until:
 - 30 Month Stay has Ended
 - Injunction Prohibiting Marketing Expired
 - Statutory Timeframes for RLD
Exclusivity Expired

Waivers & Relinquishment

- Applicants May Waive Exclusivity
- Applicants May Relinquish Eligibility for Exclusivity

Multiple Strength/Drug Product Exclusivity

- Each Strength of a Drug Product is Independently Eligible for Exclusivity