

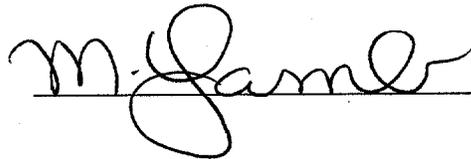
M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 8, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Micro Review Process

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: Micro Review Process
Presented for: FDA Technical Workshop
Date Presented: 10/18/99
Presented by: Joe Buccine
Number of Pages: 9



Attachment

3868 '00 FEB 11 A925

90S-0308

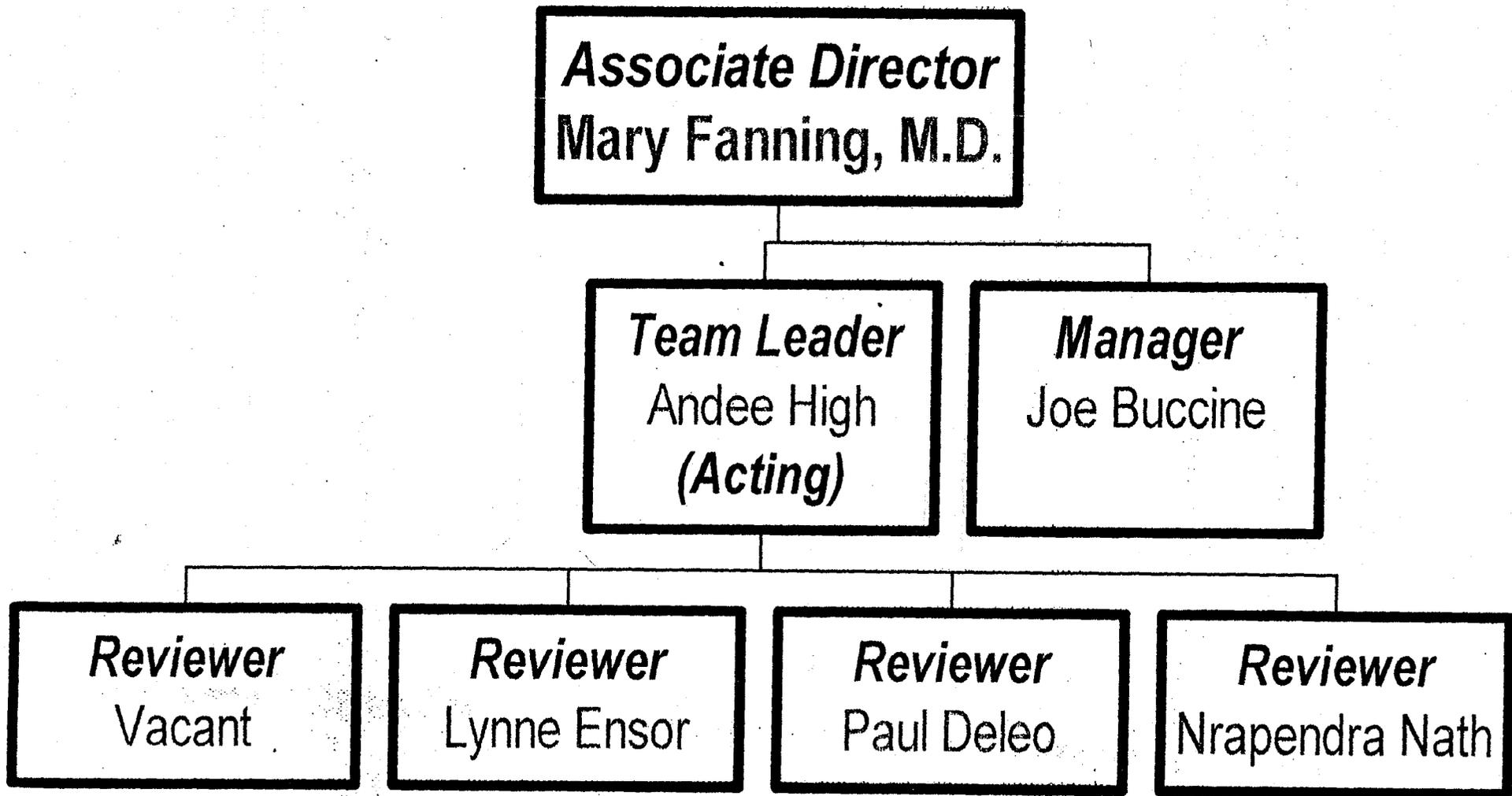
M649

Joe Buccine

Microbiology Review Process

October 18, 1999

Microbiology Team Structure



Micro Project Manager's Roles and Responsibilities

- Assist the team leader in prioritizing and assigning reviews
- Support and coordinate timely reviews
- Initiate and coordinate consults
- Collaborate with the chemistry project managers to assure timely actions and communications

ANDA Review Components

Chemistry

Bioequivalence

Labeling

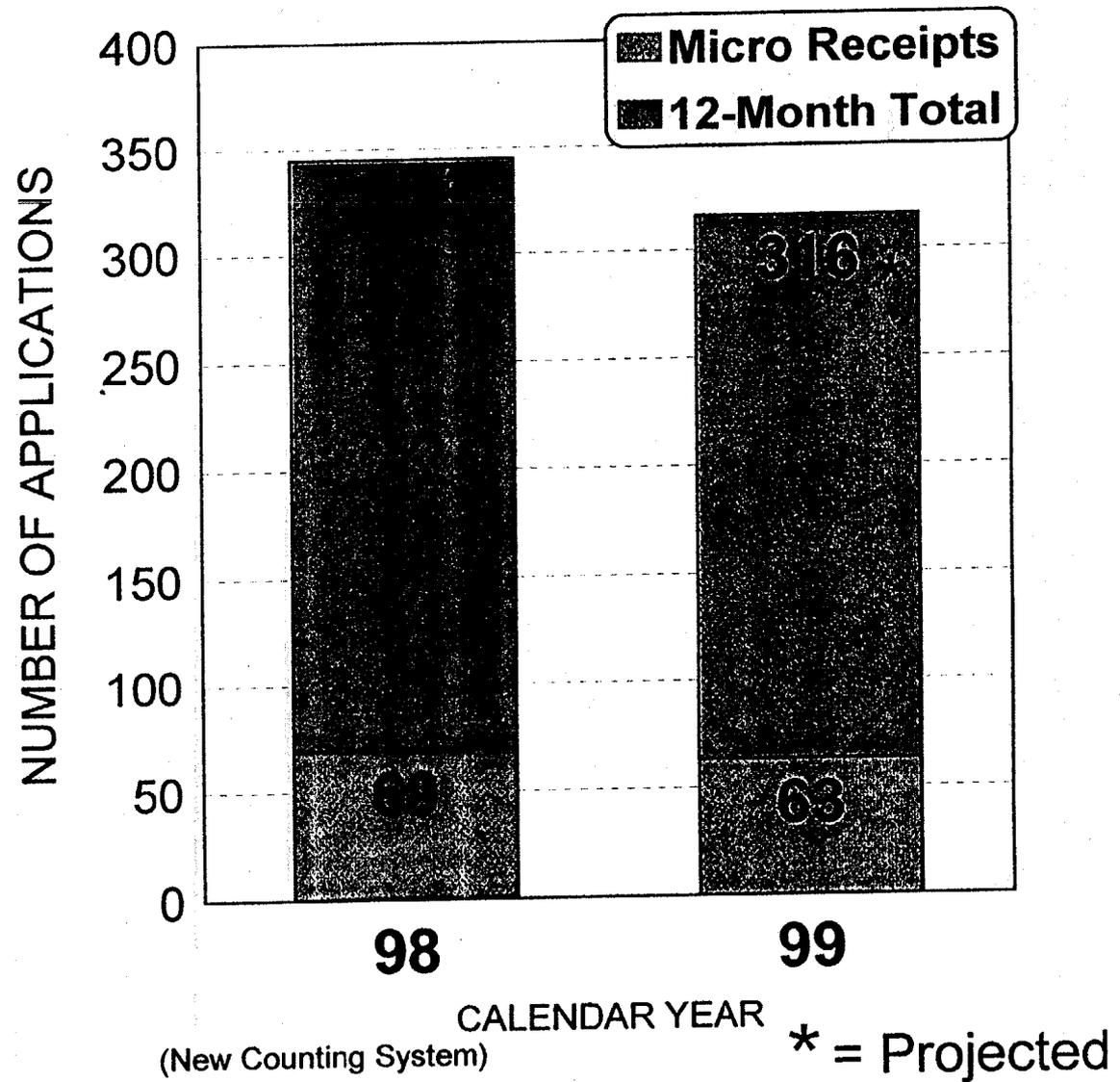
Inspections

Patent/Legal Issues

Microbiology

Microbiology Receipts in Original ANDAs

Approximately
20% of
Original
Applications
contain
Sterility Data



Microbiology Review Backlog

How and when did it occur?

What is OGD doing about it?

Performance Goals

Short Term:

No Delayed Drug Approvals

Reduce Overdue Applications

Long Term:

Control the Backlog

Eliminate Consults

What Firms Can Do To Help

- Highlight in the cover letter that the submission contains micro information
- Separate the sterility information from CMC information

Joe Buccine, R.Ph., M.G.A.

Microbiology Project Manager

301 827-5754