DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Murase Glass Co., Ltd.
Attn: Shigemitsu Murase, President
1-20-9 Yahiro Sumida-ku,
Tokyo, JAPAN 131-0041

NOV - 6 2006

Dear Sir/Madam:

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF Number Assigned: 19895 **Date of Submission:** October 24, 2006

DMF Type: III

Title of Submission: Ampoule, Vial, and Screw Vial **as manufactured in** Chiba, Japan

Holder of Submission: Murase Glass Co., Ltd.

Submitted by: Center For Regulatory Services, Inc.

Agent(s): Center For Regulatory Services, Inc.

All subsequent correspondence to this DMF should be identified with the information as provided above. Submissions to the DMF should be forwarded in duplicate.

Your DMF will be reviewed only in connection with the New Drug Applications, Abbreviated New Drug Applications, Investigational New Drug Applications or any DMFs it is intended to support.

The holder of the DMF is responsible for compliance with the Regulation Title 21 Code of Federal Regulations Part 314.420 as interpreted in "The Guideline for Drug Master Files" [HEW (FDA) 79-3072. www.fda.gov/cder/guidance/dmf.htm. You are expected to:

- Adhere to the statement of the commitment you have provided
- Provide to the FDA by submission to the DMF in two copies:
  - Amendments to the DMF. The types of information to be submitted in an amendment include:
    - any change or addition to the technical information, adequately cross-referenced to the date(s), volume(s), section(s), and/or page number(s) affected.