ESTABLISHMENT EVALUATION REQUEST

Date:

Request Type (Check One):
Original □ Follow-up □

Reviewer's Name, Division, Mail Code, Phone Number:

Application Number and Type (BLA, PMA, NDA, ANDA) or Supplement Number and Type (i.e., PAS, CBE, CBE30):

Brief Description of the Application or Detailed Summary of the Supplement, including product(s) and establishment(s) (indicate if the supplement represents an improvement or change intended to help the applicant or location achieve compliance):

Applicant:
Address:
City, State, and Zip Code:
U.S. License Number (if any)
FEI Number:

Name, Complete Address, U.S. License Number (if applicable), and <u>FEI NUMBER OF ALL MANUFACTURING LOCATIONS</u> included in the pending application or supplement. Note: Compliance status check requests for firms located in the U.S. will be returned to the reviewer if a FEI number is not provided. The FEI number is required to query the field data systems.

1,	**2,**
3,	**4,**
5,	**6,**

CSO:
Date Received:
cGMP Compliance Status: