MAKING A REQUEST FOR A CURRENT GOOD MANUFACTURING PRACTICE (cGMP) STATUS FOR APPROVAL PACKAGE

I. PURPOSE OF GUIDE

This guide describes the procedures for requesting a current good manufacturing practice (cGMP) status check to assure that a firm has the capability to conduct operations as required by the appropriate cGMPs (21 CFR Part 211, 225, or 226).

II. BACKGROUND

Sponsors must demonstrate, among other things, that the methods used in, or the facilities and controls used for, the manufacture, processing, and packaging of a new animal drug are adequate to assure and preserve its identity, strength, quality, and purity before FDA can approve a New Animal Drug Application (NADA)[1] or an Abbreviated New Animal Drug Application (ANADA).[2] The regulations set forth in 21 CFR Parts 210 through 226 contain the minimum cGMP for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packaging or holding of a drug to assure that such drug meets the requirements of the Federal Food, Drug, and Cosmetic Act (the Act).

[1] Section 512(d)(1)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(d)(1)(C)).
[2] Section 512(c)(2)(A)(i) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(c)(2)(A)(i)).

III. WHICH SUBMISSIONS REQUIRE A CGMP STATUS CHECK?

A cGMP Status Check should be requested prior to recommending approval of the following applications:

a. Administrative NADA

b. Traditional NADA [original application (A) or reactivation of original (E)]

c. ANADA [original application (A) or reactivation of original (E)]

d. Supplemental NADA or ANADA [original supplement (C) or reactivation of original (R)].

A status check should not be requested for combination applications submitted pursuant to 512 (d) (4) ("ADAA" combinations).

IV. WHEN SHOULD A REQUEST FOR CGMP STATUS CHECK BE INITIATED?

The cGMP Status Check should be initiated immediately for all applications as stated in section III above, unless the Chemistry, Manufacturing and Controls Section is included as part of the current submission.

V. HOW TO REQUEST A CGMP STATUS CHECK

All cGMP Status Checks should be sent to a mailbox entitled "CVMGMPSTATUS." Designated personnel in the Division of Manufacturing Technologies will check this mailbox daily. All requests received will be completed within 5 working days.

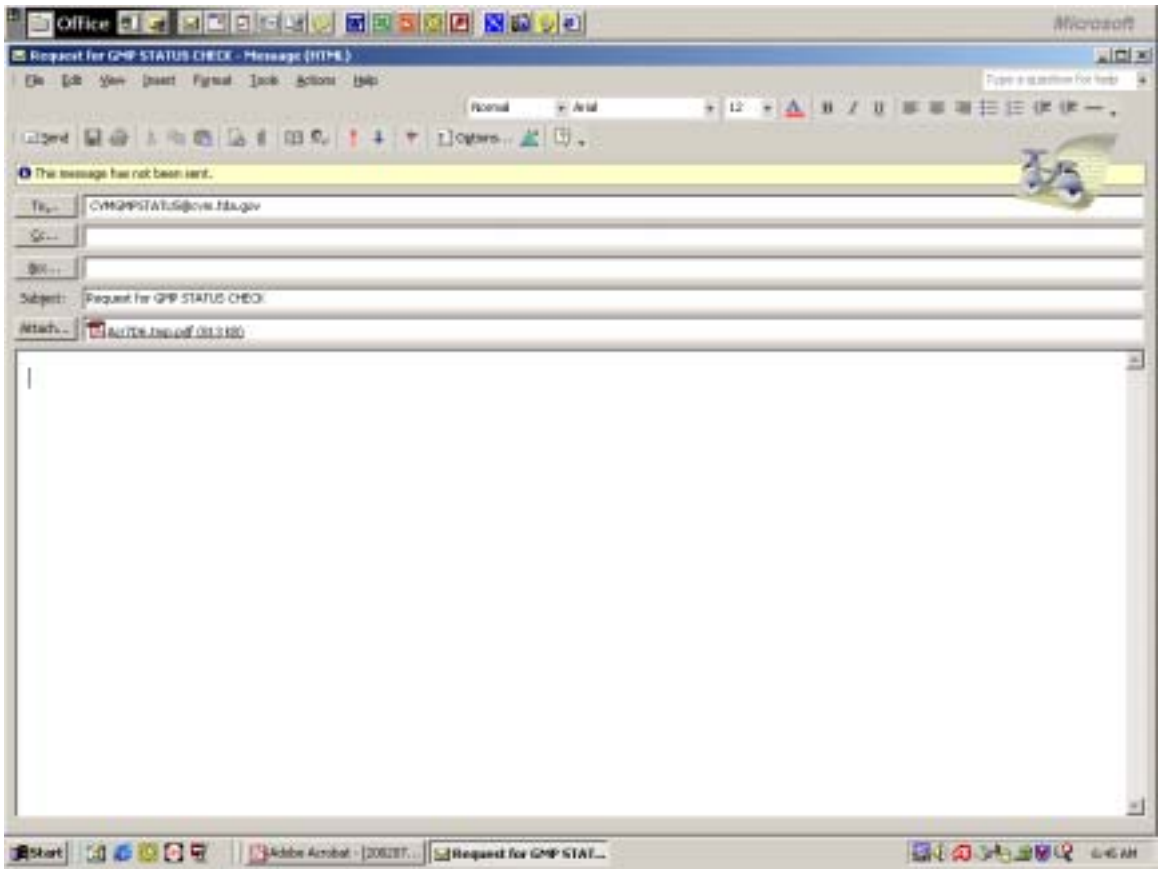
For an Administrative NADA, the Document Control Unit will send a message to the "CVMGMPSTATUS" mailbox when the submission is coded in STARS as an Administrative NADA (Action Code 250). The results of the Status Check will be e-mailed to the assigned reviewer or division director.

For a traditional NADA, ANADA, supplemental NADA or ANADA, the primary reviewer or designated personnel responsible for preparing the approval package should confirm that all applicable manufacturing and testing facilities are still in compliance with cGMP. This person should complete the form "Request for cGMP Status Check."

The Division of Manufacturing Technologies cannot proceed with the STATUS CHECK if not all fields are completed.

Forward the form to the Division of Manufacturing Technologies by using the "Send to CVMGMPSTATUS Mailbox" button (see below) located at the bottom of the form.

Click Send again once the Outlook screen is open (see below).



VI. DOCUMENTATION ON CGMP STATUS CHECK

- The Division of Manufacturing Technologies will e-mail the results of the Status Check to the primary reviewer or designated personnel who initiated the request.

- The primary reviewer or designated personnel should include a hard copy printout of the Status Check e-mail in Folder "B" of the approval package.

VII. REFERENCES

Coding an NADA submission as an Administrative NADA-Use of 250/251 action codes

Form: Request for cGMP Status Check