MAKING A REQUEST FOR A CURRENT GOOD MANUFACTURING PRACTICE (CGMP) STATUS CHECK FOR AN APPROVAL PACKAGE

I. PURPOSE

This document 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) or an abbreviated new animal drug application (ANADA)[1,2]. The regulations 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).

III. WHICH SUBMISSIONS REQUIRE A STATUS CHECK?

Request a cGMP Status Check prior to recommending approval of the following applications:

1. Administrative (A)NADA
2. Traditional (A)NADA [original application (A) or reactivation of an original (E)]
3. Supplemental (A)NADA [original supplement (C) or reactivation of an original (R)]

[1] For NADAs see Section 512(d)(1)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(d)(1)(C)).

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

Do not request a status check for combination applications submitted pursuant to 512(d)(4) (Animal Drug Availability Act or "ADAA" combinations).

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

In most cases, initiate the cGMP Status Check immediately when beginning to assemble the approval package for all applications listed in section III above. However, if a non-administrative original or supplemental (A)NADA has a CMC consult, the status check should be requested after the CMC consult has been returned.

V. HOW TO REQUEST A STATUS CHECK

Request a cGMP Status Check by sending an email to the Outlook mailbox entitled “CVMGMPSTATUS". Designated personnel in the Division of Manufacturing Technologies will check this mailbox daily. All requests received will be completed within five working days.

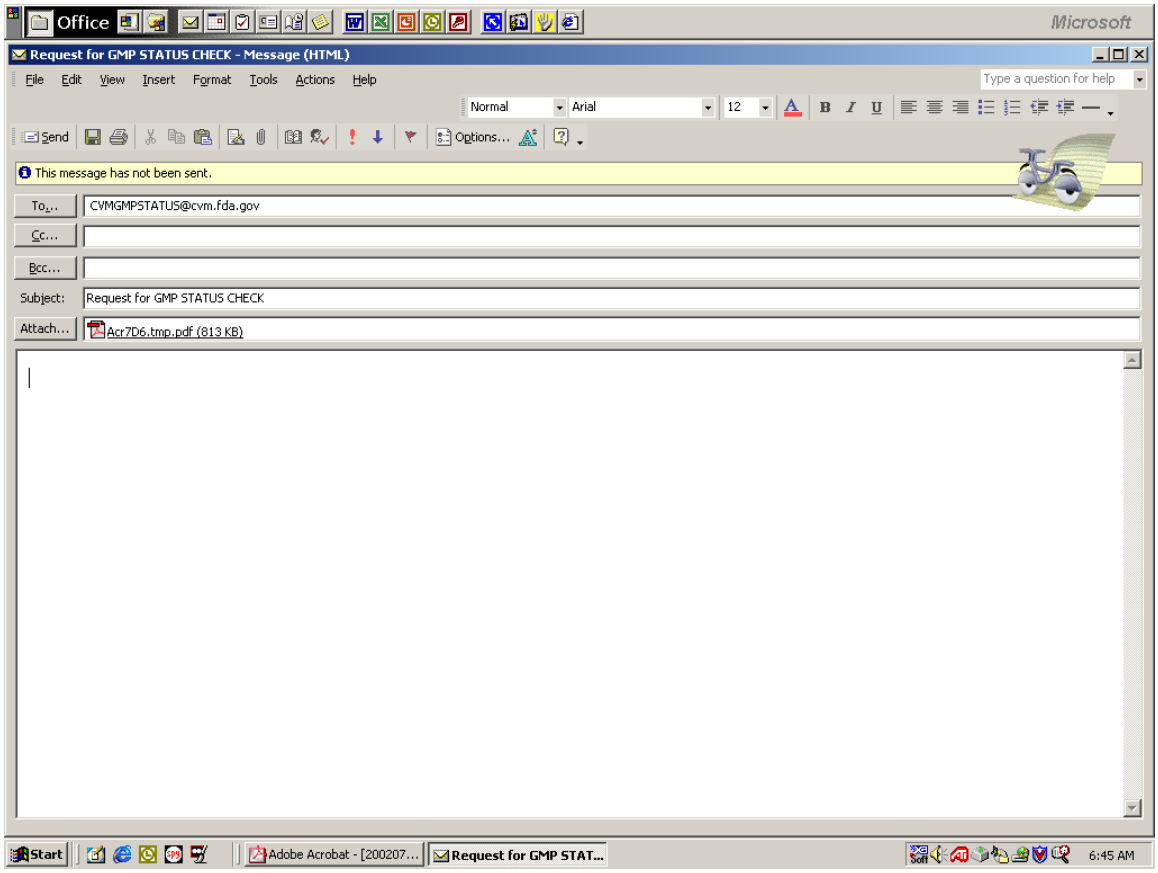
The primary reviewer or designated personnel responsible for preparing the approval package will confirm that all applicable manufacturing and testing facilities are still in compliance with cGMP. Do this by completing the form "Request for cGMP Status Check". The cGMP Status Check Form is on the ONADE Forms page of the ONADE SharePoint site.

The Division of Manufacturing Technologies cannot proceed with the cGMP status check unless all fields on the form 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.

Note that the software used to create the fillable PDF form does not allow the user to type symbols on the form.

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



VI. DOCUMENTATION OF THE STATUS CHECK

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

The primary reviewer or designated person will include a copy of the Status Check e-mail in Folder "B" of the approval package.

VII. REFERENCES

Compliance Program Guidance Manual (CPGM) 7368.001

VIII. VERSION HISTORY

November 16, 2001 – Original version

June 24, 2003 – Updated

July 7, 2009 – Editorial and clarifying changes made and descriptions for how to find documents were added in place of links to the intranet

February 13, 2017 – Clarification of the process used for Administrative (A)NADAs

October 17, 2017 – Clarification of when a GMP status check should be requested