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 (abbreviated) new animal drug application [(A)NADA].[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 (FD&C Act).

III. WHICH SUBMISSIONS REQUIRE A STATUS CHECK?

Request a CGMP status check prior to recommending approval of the following:

1. administrative (A)NADA;
2. traditional (A)NADA [original application (A) or reactivation (E)]; and
3. supplemental (A)NADA [original supplement (C) or reactivation (R)].

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. However, if a non-

[1] For NADAs, see Section 512(d)(1)(C) of the FA&C Act (21 U.S.C. 360b(d)(1)(C))

[2] For ANADAs, see Section 512(c)(2)(A)(i) of the FD&C Act (21 U.S.C. 360b(c)(2)(A)(i)).

administrative original or supplemental (A)NADA has a CMC consult, a separate GMP status check is not needed unless the CMC consult was returned more than 60 days before the final close-out date. For the CMC consult, if the GMP status is acceptable, then there will be no incomplete comment regarding GMP status and if the GMP status is unacceptable for one or more facilities, then there will be a specific incomplete comment for each facility with an unacceptable GMP status. This comment usually states that an acceptable GMP status is pending for the specific facility.

V. HOW TO REQUEST A STATUS CHECK

Request a CGMP Status Check by issuing a consult, including the relevant (J)INAD number for an administrative original, to the relevant team in the Division of Manufacturing Technologies (DMT) via Appian (per P&P 1243.3200). In the instruction field, include "GMP status check. Please return consult within 10 days." All requests received will be completed within ten (10) working days. The DMT reviewer confirms that all applicable manufacturing and testing facilities are still in compliance with CGMPs.

VI. DOCUMENTATION OF THE STATUS CHECK

The DMT reviewer completes the Appian workflow and returns the consult with one of the following the statements in the comment field: "The GMP status is acceptable" or "The GMP status is unacceptable".

VII. REFERENCES

Compliance Program Guidance Manual (CPGM)

CPGM 7368.001 https://www.fda.gov/media/74723/download

CVM Program Policy and Procedures Manual – ONADE Reviewer's Chapter

1243.3200 Routing a Request to Obtain a Consulting Review of a Submission Tracking and Reporting System (STARS) Submission

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.

June 2, 2021 – Quality system review was completed, and no substantive edits were required. Minor formatting updates were made.

July 11, 2022 – Quality system review for minor formatting updates.

September 1, 2022 - Updated to reflect a change from the GMP status check form to the use of an Appian consult.

December 13, 2022 – In section V, minor editorial corrections made and added instructions to always indicate the purpose of the consult request and boilerplate provided for the instructions.

February 5, 2024 – Quality management review completed on the document and no revisions were needed at this time. The document was put into the current office template and format. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.