
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

UNITED STATES (U.S.) AGENTS

I.	Purpose	1
II.	Definition of a U.S. agent	1
III.	When a U.S. agent is required	1
IV.	Administrative process for a foreign sponsor to appoint a U.S. agent	2
V.	The role of consultants.....	3
VI.	Communication responsibilities	3
VII.	References	3
VIII.	Version history.....	4

I. PURPOSE

This document describes the Office of New Animal Drug Evaluation (ONADE)'s procedures for working with United States (U.S.) agents, including:

- The definition of a U.S. agent
- When a U.S. agent is required
- The administrative process for a foreign sponsor to appoint a U.S. agent
- The role of consultants
- Communication responsibilities

II. DEFINITION OF A U.S. AGENT

A U.S. agent is a person who resides or maintains a place of business within the U.S., and who serves as the responsible official for a foreign sponsor (an applicant who does not reside or maintain a place of business within the U.S.).¹ The U.S. agent must be available for contact by email and/or telephone during regular business hours.

III. WHEN A U.S. AGENT IS REQUIRED

A. Submissions to Investigational and Application File Types

A U.S. agent is required for submissions to generic investigational new animal drug (JINAD) or investigational new animal drug (INAD) (collectively referred to as [J]INAD) files, and abbreviated new animal drug application (ANADA) or new animal drug application (NADA) (collectively referred to as [A]NADA) files.

¹ 21 CFR § 514.1(a): "Applications to be filed under section 512(b) of the act...must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of, and must be countersigned by, an authorized attorney, agent, or official residing or maintaining a place of business within the United States."

ONADE extends the U.S. agent requirement to submissions to (J)INAD files belonging to foreign sponsors because, under the phased review process, we are making application-level decisions about the acceptability of data or information submitted. Phased review submissions are intended to support a future decision to approve an application. For the sake of simplicity, ONADE applies this requirement to all investigational submissions rather than specifying whether a U.S. agent is required for each individual submission type.

Electronic (eSubmitter) submissions to these files must be made by the U.S. agent or their representative (a colleague to whom the U.S. agent delegates eSubmitter responsibility). Legally, a foreign sponsor can make submissions that are countersigned by a U.S. agent. Because ONADE does not currently have an acceptable way to obtain a countersignature in eSubmitter, submissions to (J)INAD and (A)NADA files must be submitted by the U.S. agent or their representative. Electronic submissions to these files that are not made by the U.S. agent or their representative will be closed out with the final action Refuse to Review (RTR) or Refuse to File (RTF).²

Paper submissions made by a foreign sponsor and countersigned by a U.S. agent can be processed for review.

B. Submissions to Other File Types

A U.S. agent is not required for submissions to files other than (J)INADs and (A)NADAs. Submissions to other files (e.g., General Correspondence [GC] or Veterinary Master File [VMF]) do not need to be countersigned by a U.S. agent and may be submitted directly by a foreign sponsor for review.

Note: While a U.S. agent is not required for submissions to a VMF, foreign manufacturing facilities are required to designate a U.S. agent.³ ONADE encourages foreign manufacturing facilities to identify the U.S. agent in their VMF using the process below.

IV. ADMINISTRATIVE PROCESS FOR A FOREIGN SPONSOR TO APPOINT A U.S. AGENT

When the initial submission (A-0000) to establish a file is made by the U.S. agent, the U.S. agent should include a signed letter from the foreign sponsor stating that they are appointing [person] as their U.S. agent. The U.S. agent must be a specific person and not a company (for example, "John Smith" rather than "John Smith Consulting"). The letter appointing the U.S. agent should also contain contact information for the U.S. agent including their email address, telephone number, and mailing address.

The U.S. agent for a foreign sponsor may be changed through a general correspondence (G) submission to all applicable files; the G submission should include a signed letter from the foreign sponsor as outlined above. Foreign sponsors may appoint different U.S. agents to different files, so we need a record in each file of who the U.S. agent is. Ideally with any change in U.S. agent, the current U.S. agent will

² See P&P 1243.2050 Refuse to File and Refuse to Review

³ 21 CFR § 207.69(b)

submit a G submission notifying ONADE of the new U.S. agent taking responsibility from that point on. If a U.S. agent relationship terminates without a new U.S. agent being identified, the current U.S. agent should submit a G submission stating that they are no longer serving as the U.S. agent from that point on. If the current U.S. agent is unable to make this submission, we would accept this notification directly from the foreign sponsor. The foreign sponsor must appoint a new U.S. agent, who should inform ONADE by making a G submission stating they are the U.S. agent, before we can accept additional submissions to a (J)INAD or (A)NADA file.

A sponsor may appoint only one U.S. agent to a file at a time.

The G submission will be assigned to the project manager (PM) for a pioneer (INAD or NADA) sponsor. G submissions to other file types will be assigned to the appropriate review division. If we receive a linked G submission across diverse file types, the submission will be assigned according to the majority of impacted files.

The primary reviewer assigned to the G submission will close it out with final action code 007, SUBMISSION FILED WITH NO REVIEW DOCUMENTATION; NO LETTER SENT (FNR).

V. THE ROLE OF CONSULTANTS

A foreign sponsor may engage consultants in addition to a U.S. agent.

For (J)INAD and (A)NADA files, all electronic submissions must be made by the U.S. agent or their representative, and any paper submissions must be countersigned by the U.S. agent, as discussed above.

Submissions to other file types may be made directly by a consultant.

VI. COMMUNICATION RESPONSIBILITIES

When a U.S. agent is appointed for a file, ONADE will copy the U.S. agent or their representative on any communication we initiate with the foreign sponsor or consultants. ONADE expects the U.S. agent or their representative to attend any formal meetings held under the file. If the foreign sponsor initiates communication with us that does not include the U.S. agent (such as sending an email or requesting a telephone conversation), we will remind the foreign sponsor that we recommend the U.S. agent or their representative be included in any communication between ONADE and the foreign sponsor.

VII. REFERENCES

Code of Federal Regulations

Part 514 – New Animal Drug Applications

§514.1 Applications

Part 207 - Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code

§207.69 What are the requirements for an official contact and a United States agent?

CVM Program Policy and Procedures Manual

1243.2050 Refuse to File and Refuse to Review

VIII. VERSION HISTORY

May 28, 2020 – Original version. This document takes ONADE policy and formalizes it in this policy and procedure document.