
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

SPONSOR REQUESTS TO RESERVE AN (A)NADA NUMBER

I. Purpose.....	1
II. How sponsors request to reserve an (A)NADA number	1
III. Processing requests to reserve (A)NADA number	1
IV. Maintaining the spreadsheet in sharepoint	2
V. Version history	2

I. PURPOSE

This document describes when the Office of New Animal Drugs (ONADE) will agree to a sponsor request to reserve a new animal drug application (NADA) number or abbreviated new animal drug application (ANADA) number and how ONADE processes such requests.

II. HOW SPONSORS REQUEST TO RESERVE AN (A)NADA NUMBER

We will allow sponsors to request to reserve an (A)NADA number only when they have submitted all of their major technical sections and intend to submit an administrative (A)NADA. Sponsors should be advised to submit these requests via telephone or email to ONADE project managers (PM) for NADAs, or the team leaders (TL) within the Division of Generic Animal Drugs for ANADAs.

III. PROCESSING REQUESTS TO RESERVE (A)NADA NUMBER

Once a request is received, the PM or TL will fill out and send a STARS Pre-Assigned (A)NADA Number Request Form to the Records and Information Management Team (RIM) Team to obtain a number . The RIM Team will create a new (A)NADA number in STARS and inform the PM or TL by email once it is created. The PM or TL will then create a "Q" submission with "other" as the purpose of submission, under the referenced investigational new animal drug (INAD) or generic investigational new animal drug (J)INAD file. The PM or TL will draft a letter to the sponsor containing the reserved (A)NADA number. The letter will explain that this number is only valid for 18 months (540 d) from the date of the letter, and if the sponsor submits their (A)NADA using this number after 18 months (540 d), they will be issued a new number as the old one will have been voided. Because the Q submission results in a paper letter that will be mailed to the sponsor the PM or TL may call or email the sponsor to share the number with them in advance of them receiving the acknowledgement letter. The PM or TL will enter the (A)NADA numbers as assigned into the spreadsheet.

IV. MAINTAINING THE SPREADSHEET IN SHAREPOINT

A spreadsheet will be maintained and used to track the reserved (A)NADA numbers and monitor their individual expiry periods. For (A)NADA numbers not used within the 18 month expiry period, a representative of the Business Informatics (BI) team will notify the RIM Team by submitting a STARS correction form requesting the number be voided. Once the number(s) have been voided, the RIM Team will notify the representative of the BI team and they will update the spreadsheet accordingly.

V. VERSION HISTORY

June 23, 2016 – original version