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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER’S CHAPTER

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**SPONSOR REQUESTS TO RESERVE AN APPLICATION NUMBER FOR A NEW ANIMAL DRUG OR ABBREVIATED NEW ANIMAL DRUG APPLICATION**

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**I. PURPOSE**

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

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

We allow sponsors to request to reserve an application number when they have submitted all of the major technical sections required for an application and intend to submit an administrative (A)NADA or when they intend to submit a traditional (non-administrative) application. Sponsors should be advised to submit these requests via telephone or email. Requests to reserve NADA numbers should be sent to ONADE project managers (PM). Requests to reserve ANADA numbers should be sent to the team leaders (TL) in the Division of Generic Animal Drugs (DGAD).

**III. PROCESSING REQUESTS TO RESERVE AN (A)NADA NUMBER**

Once a request is received, the PM or TL sends an email to the Records and Information management (RIM) Team<sup>1</sup> requesting a Submission Tracking and Reporting System (STARS) Pre-Assigned (A)NADA Number. The subject line of the email should be Reserve Application Number. The RIM Team creates a new (A)NADA number in STARS and emails the PM or TL once it is created. The PM or TL then creates a Q submission under the referenced (generic) investigational new animal drug ((J)INAD) file and puts the word ‘other’ in the purpose of submission. The PM or TL drafts a letter to the sponsor containing the reserved application number. The letter explains that the reserved number is only valid for 18 months (540 days) from the date of the letter, and if the sponsor submits their (A)NADA using this number after 18 months (540 days), 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 application number with them in advance of the sponsor receiving the acknowledgement letter. The PM or TL enters the (A)NADA numbers as assigned into the spreadsheet located on the ONADE Reviewer Reference Page in SharePoint.<sup>2</sup>

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<sup>1</sup> Internal information redacted.

<sup>2</sup> Internal information redacted.

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#### IV. MAINTAINING THE SPREADSHEET IN SHAREPOINT

The spreadsheet of reserved (A)NADA numbers is used to track the reserved (A)NADA numbers and monitor their individual expiry periods. For NADA numbers not used within the 18-month expiry period, the PM who reserved the application number notifies the RIM Team to void the application number by sending an email to the RIM Team<sup>3</sup> requesting the number be voided. For reserved ANADA numbers that have not been used within the 18-month expiry period, a DGAD TL sends an email to the RIM Team requesting the number be voided. The subject line for the email should be Void Application Number. Once the number(s) have been voided, the RIM Team notifies the PM or TL who sent the email request. The PM or TL then updates the spreadsheet accordingly.

#### V. VERSION HISTORY

June 23, 2016 – original version

May 20, 2020 – updated to current format. The title was updated, and section IV. was revised to remove the Business Informatics Team from the process of maintaining the spreadsheet. The process from this point on will be that the project managers and for generic applications the team leaders from the Division of Generic Animal Drugs will maintain the spreadsheet of application numbers.

June 30, 2020 - Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

December 1, 2020 – Updated to indicate that sponsors who intend to submit a traditional application (non-administrative application) can also request to reserve an application number and to update the link to the ONADE Form.

February 14, 2022 - Quality system review conducted of the document and no updates or revisions were necessary at this time.

July 15, 2022 – Quality systems review for minor formatting updates.

October 27, 2022 – Updated to replace links for changes to SharePoint ONADE Reference Reviewer Page.

June 6, 2023 - Quality system review conducted of the document and no updates or revisions were necessary at this time. 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.

December 6, 2023 – Updated sections III. and IV. The STARS Correction Request Form has been retired. The instructions are now to send the request to reserve an application number and to void a reserved application number to the RIM Team directly.

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<sup>3</sup> Internal information redacted.