

1 **Animal Generic Drug User Fee Act Reauthorization**
2 **Performance Goals and Procedures – Fiscal Years 2014**
3 **Through 2018**

4 The goals and procedures of the Food and Drug Administration (FDA or the Agency) as
5 agreed to under the "Animal Generic Drug User Fee Act of 2013" are summarized as
6 follows:

7 **Application/Submission Goals**

8 1. Original Abbreviated New Animal Drug Applications (ANADAs) and
9 Reactivations

10 Review and act on 90 percent of non-administrative original ANADAs within 270
11 days after the submission date.

12 An application is incomplete if it would require additional data or information to
13 enable the Agency to complete a comprehensive review of the application and reach a
14 decision on the issue(s) presented in the application. If the Agency determines that
15 the deficiencies are not substantial, the Agency will review and act on 90 percent of
16 reactivated applications within 190 days after the reactivated ANADA submission
17 date. This shorter review time for reactivated ANADAs for which the deficiencies
18 are determined not to be substantial is not intended to prevent the use of minor
19 amendments during Agency review of an application. If the Agency determines that
20 the deficiencies are substantial or new substantial information is provided, the
21 Agency will review and act on 90 percent of reactivated applications within 270 days
22 after the reactivated ANADA submission date.

23 Administrative ANADAs

24 Review and act on 90 percent of administrative ANADAs (ANADAs submitted after
25 all scientific decisions have been made in the JINAD process, i.e., prior to the
26 submission of the ANADA) within 100 days after the submission date.

27 2. Manufacturing Supplemental ANADAs and Reactivations

28 Review and act on 90 percent of manufacturing supplemental ANADAs within 270
29 days after the submission date.

30 A submission is incomplete if it would require additional data or information to
31 enable the Agency to complete a comprehensive review of the submission and reach a
32 decision on the issue(s) presented in the submission. If the Agency determines that
33 the deficiencies are not substantial for manufacturing supplements requiring prior
34 approval according to 21 CFR 514.8(b), the Agency will permit the manufacturing
35 supplements to be resubmitted as "Supplement-Changes Being Effected in 30 Days"

36 as described in 21 CFR 514.8(b)(3). If the Agency determines that the deficiencies
37 are substantial or new substantial information is provided, the Agency will review
38 and act on 90 percent of reactivated manufacturing supplements within 270 days after
39 the re-submission date.

40 3. Generic Investigational New Animal Drug (JINAD) Study Submissions

41 Review and act on 90 percent of JINAD study submissions within 270 days after
42 submission date.

43 A submission is incomplete if it would require additional data or information to
44 enable the Agency to complete a comprehensive review of the study submission and
45 reach a decision on the issue(s) presented in the submission. If the Agency
46 determines that the deficiencies are not substantial, the Agency will review and act on
47 90 percent of resubmitted JINAD study submissions within 90 days after the
48 resubmission date. This shorter review time for resubmitted JINAD study
49 submissions is not intended to prevent the use of minor amendments during Agency
50 review of a study submission. If the Agency determines that the deficiencies are
51 substantial or new substantial information is provided, the Agency will review and act
52 on 90 percent of resubmitted JINAD study submissions within 270 days after the
53 resubmission date.

54 4. JINAD Protocols

55 Review and act on 90 percent of JINAD submissions consisting of protocols without
56 substantial data, that the Agency and the sponsor consider to be an essential part of
57 the basis for making the decision to approve or not approve an ANADA or
58 supplemental ANADA, within 100 days after the submission date.

59 Permit comparability protocols as described in 21 CFR 514.8(b)(2)(v) to be submitted
60 as protocols without substantial data in a JINAD file. The Agency will review and
61 act on 90 percent of JINAD submissions consisting of protocols without substantial
62 data within 100 days after the submission date of the protocol. For potentially more
63 complex comparability protocols, for example sterile process validation protocols, the
64 sponsor should discuss and have Agency concurrence regarding the appropriate filing
65 strategy.

66 For the application/submission goals above, the term "review and act on" is understood to
67 mean the issuance of a complete action letter after the complete review of an original
68 ANADA, supplemental ANADA, or JINAD submission which either (1) approves an
69 original or supplemental ANADA or notifies a sponsor that a JINAD submission is
70 complete or (2) sets forth in detail the specific deficiencies in such original or
71 supplemental ANADA or JINAD submission and, where appropriate, the actions
72 necessary to place such an original or supplemental ANADA or JINAD submission in
73 condition for approval ("incomplete letter"). Within 30 days of submission, FDA shall
74 refuse to file an original or supplemental ANADA, or their reactivation, which is

75 determined to be insufficient on its face or otherwise of unacceptable quality for review
76 upon initial inspection as per 21 CFR 514.110. Thus, the agency will refuse to file an
77 application containing numbers or types of errors, or flaws in the development plan,
78 sufficient to cause the quality of the entire submission to be questioned to the extent that
79 it cannot reasonably be reviewed. Within 60 days of submission, FDA will refuse to
80 review a JINAD submission which is determined to be insufficient on its face or
81 otherwise of unacceptable quality upon initial inspection using criteria and procedures
82 similar to those found in 21 CFR 514.110. A decision to refuse to file an application or
83 to refuse to review a submission as described above will result in the application or
84 submission not being entered into the cohort upon which the relevant user fee goal is
85 based. The agency will keep a record of the numbers and types of such refusals and
86 include them in its annual performance report.

87
88 FDA may request minor amendments to original or supplemental ANADAs and JINAD
89 submissions during its review of the application or submission. At its discretion, the
90 Agency may extend an internal due date (but not a user fee goal) to allow for the
91 complete review of an application or submission for which a minor amendment is
92 requested. If a pending application is amended with significant changes, the amended
93 application may be considered resubmitted, thereby effectively resetting the clock to the
94 date FDA received the amendment. The same policy applies for JINAD submissions.

95
96 Sponsors are not required to submit study protocols for review. However, for each
97 voluntarily submitted protocol for a study that the Agency and the sponsor consider to be
98 an essential part of the basis for making the decision to approve or not approve an
99 original or supplemental ANADA, the Agency will issue a complete action letter
100 providing comments resulting from a complete review of the protocol. The complete
101 action letter will be as detailed as possible considering the quality and level of detail of
102 the protocol submission; will include a succinct assessment of the protocol; and will state
103 whether the Agency agrees, disagrees, or lacks sufficient information to reach a decision
104 that the protocol design, execution plans, and data analyses are adequate to achieve the
105 objectives of the study. If the Agency determines that a protocol is acceptable, this
106 represents an agreement that the data generated by the protocol can be used to support a
107 safety or effectiveness decision regarding the subject new animal drug. The fundamental
108 agreement is that having agreed to the design, execution, or analyses proposed in
109 protocols reviewed under this process, the Agency will not later alter its perspectives on
110 the issues of design, execution, or analyses unless the Agency issues a written order that a
111 substantiated scientific requirement essential to the assessment of the study appeared
112 after the Agency's protocol assessment, or public or animal health concerns unrecognized
113 at the time of protocol assessment under this process are evident.

114 The term "submission date" is understood to mean the date the FDA Center for
115 Veterinary Medicine (CVM) Document Control Unit (DCU) receives an application or
116 submission. DCU date stamps an application or submission on the day of receipt.

117 **Work Queue Review Procedures**

118 The Agency will review all submissions in accordance with procedures for working
119 within a queue. An application/submission that is not reviewed within the applicable
120 Application/Submission Goal time frame will be reviewed with the highest possible
121 priority among those pending.

122 **Amending Similar Applications and Submissions**

123 The Agency and regulated industry agree that applications and submissions to the
124 Agency will be complete and of sufficient quality to allow the Agency's complete and
125 timely review. The Agency will refuse to file poor quality and incomplete applications
126 and submissions rather than allowing them to serve as "placeholders" in the review queue
127 that are subsequently amended to add the missing or inadequate portions.

128
129 The Agency recognizes that there are circumstances in which a controlled amendment
130 process can make the review of similar, pending submissions more efficient, without
131 compromising the sponsor's responsibility for high quality submissions. Thus, if the
132 Agency requests an amendment to a non-administrative original ANADA, manufacturing
133 supplemental ANADA, JINAD study submission, or a JINAD protocol submission (a
134 "CVM-initiated amendment"), or issues an incomplete letter for such an application or
135 submission, a sponsor may request to amend other, similar applications or submissions it
136 has pending with the Agency ("sponsor-initiated amendment(s)") in accordance with the
137 following criteria:

- 138 1. The amended information for these similar applications or submissions must be
139 the same as in the CVM-requested amendment or incomplete letter; and
- 140 2. The amended information must not significantly change the pending application
141 or submission; and
- 142 3. The amended information for these similar applications or submissions must be
143 submitted no later than:
 - 144 a. 120 days after the submission date for one of these pending non-
145 administrative original ANADA, manufacturing supplemental ANADA,
146 or JINAD study submissions; or
 - 147 b. 50 days after the submission date for one of these pending JINAD protocol
148 submissions.

149 If the Agency determines that the above criteria have been met, it will not change the user
150 fee goal for a pending application or submission that has been amended by a sponsor-
151 initiated amendment. If the above criteria have not been met, the Agency may consider
152 the application or submission resubmitted on the date of the sponsor-initiated
153 amendment, thereby resetting the clock to the date FDA received the amendment.

154 **Multiple Data Submissions to the Chemistry Manufacturing Controls Technical** 155 **Section**

156 The Agency will develop and implement a two-phased Chemistry Manufacturing
157 Controls technical section review process under the JINAD file by the end of fiscal year
158 2014.

159 **Develop Question Based Review Process for Bioequivalence Submissions**

160 The Agency will develop and implement a question based review (QbR) process for
161 bioequivalence submissions by the end of fiscal year 2016. At its discretion, the Agency
162 may extend the timeline for completion if necessary, depending on available resources.

163 **Timely Foreign Pre-Approval Inspections**

164 1. The Agency and regulated industry are committed to improving the review and
165 business processes that will facilitate the timely scheduling and conducting of pre-
166 approval inspections (PAIs). To improve the timeliness and predictability of foreign
167 PAIs, sponsors may voluntarily submit 1) at the beginning of the calendar year, a list of
168 foreign manufacturing facilities that are specified in an abbreviated application,
169 supplemental abbreviated application, or generic investigational file and may be subject
170 to foreign PAIs for the following fiscal year; and 2) a notification 30 days prior to
171 submitting an abbreviated application, a supplemental abbreviated application, or generic
172 investigational file that informs the Agency that the application includes a foreign
173 manufacturing facility. Should any changes to the annual list occur after its submission
174 to the Agency, the sponsor may provide the updated information to the Agency.

175 2. The Agency will keep a record of the number of foreign PAIs conducted for
176 abbreviated applications, along with the average time for completing the PAIs, and
177 include this information in its annual performance report. The time for completing the
178 PAI is understood to mean the time from the inspection scheduling request through
179 notification to the Center of inspectional findings.

180 **Timely Meetings with Industry**

181 The Agency and the regulated industry agree that the use of both formal meetings (e.g.,
182 presubmission conferences, workshops, etc.) and informal communication by both parties
183 is critical to ensure high submission quality such that the above performance goals can be
184 achieved.

185 **Workload Adjustment**

186 The proposed amendment to the Animal Generic Drug User Fee Act of 2008 requires
187 FDA to annually adjust fee revenues after fiscal year 2014 to reflect changes in review
188 workload utilizing a weighted average of the change in the total number of abbreviated
189 applications for generic new animal drugs, manufacturing supplemental abbreviated
190 applications for generic new animal drugs, investigational generic new animal drug study
191 submissions, and investigational generic new animal drug protocol submissions. The
192 Agency will use the method detailed below to calculate the workload adjustment, and the

193 percent increase in fees will be made if the amount of the workload adjuster is equal to or
194 greater than one percent (1%). In accordance with the statute, the workload adjustment
195 will not result in fee revenues for a fiscal year that are less than the fee revenues for that
196 fiscal year as specified in the statute.

197 The term “workload adjuster” applicable to a fiscal year consists of the sum of the
198 percent of change in the total number of each of the four component submission types
199 submitted (comparing the five-year average number of such submissions for fiscal years
200 2009 – 2013 -- the base years -- to the five-year average for the most recent five-year
201 period ending June 30 before the start of the next fiscal year) times a weighting factor
202 that is the percent of direct review time spent on the each of the four component
203 submissions over the most recent five-year period.