

1 **Animal Drug User Fee Act Reauthorization Performance**

2 **Goals and Procedures – Fiscal Years 2014 Through 2018**

3 The goals and procedures of the FDA Center for Veterinary Medicine (CVM) as agreed
4 to under the "Animal Drug User Fee Amendments of 2013" are summarized as follows:

5 **Definitions**

- 6 1. For the application/submission goals below, the term "review and act on" is
7 understood to mean the issuance of a complete action letter after the complete
8 review of an animal drug application, supplemental animal drug application, or
9 investigational animal drug submission which either (1) approves an animal drug
10 application or supplemental application or notifies a sponsor that an
11 investigational animal drug submission is complete or (2) sets forth in detail the
12 specific deficiencies in such animal drug application, supplemental animal drug
13 application, or investigational animal drug submission and, where appropriate, the
14 actions necessary to place such an application, supplemental application, or
15 submission in condition for approval. Within 30 days of submission, FDA shall
16 refuse to file an animal drug application, supplemental animal drug application, or
17 their reactivation, which is determined to be insufficient on its face or otherwise
18 of unacceptable quality for review upon initial inspection as per 21 CFR 514.110.
19 Thus, the agency will refuse to file an application containing numbers or types of
20 errors, or flaws in the development plan, sufficient to cause the quality of the
21 entire submission to be questioned to the extent that it cannot reasonably be
22 reviewed. Within 60 days of submission, FDA will refuse to review an
23 investigational animal drug submission which is determined to be insufficient on
24 its face or otherwise of unacceptable quality upon initial inspection using criteria
25 and procedures similar to those found in 21 CFR 514.110. A decision to refuse to
26 file an application or to refuse to review a submission as described above will
27 result in the application or submission not being entered into the cohort upon
28 which the relevant user fee goal is based. The agency will keep a record of the
29 numbers and types of such refusals and include them in its annual performance
30 report.
- 31 2. A minor amendment is understood to mean information requested by FDA during
32 the review of the application or investigational submission. FDA may request
33 minor amendments to animal drug applications, supplemental animal drug
34 applications, and investigational animal drug submissions during its review of the
35 application or submission. At its discretion, the Agency may extend an internal
36 due date (but not a user fee goal) to allow for the complete review of an
37 application or submission for which a minor amendment is requested. If a
38 pending application is amended with significant changes, the amended application
39 may be considered resubmitted, thereby effectively resetting the clock to the date
40 FDA received the amendment. The same policy applies for investigational animal
41 drug submissions.
- 42 3. The term "end-review amendment" is understood to mean an amendment to an
43 animal drug application, supplemental animal drug application, or investigational

- 44 animal drug submission that is requested by the Agency after it has completed its
45 review of the submitted information and determines that the submission of
46 additional non-substantial data or information would likely complete the
47 application or submission. This term does not include minor amendments
48 requested by the Agency during review of applications or submissions that do not
49 impact upon the user fee goals, as described in Definitions paragraph 2 above.
- 50 4. The term “submission date” is understood to mean the date CVM’s Document
51 Control Unit (either electronically through FDA’s electronic submissions gateway
52 or via paper) receives an application or submission.
 - 53 5. The term “labeling supplement” is understood to mean certain applications as
54 described in 21 CFR 514.8(c)(2)(i)(A) and (D) that require approval of a
55 supplemental application prior to distribution of the drug made using the change.
 - 56 6. The term “presubmission conference” is understood to mean one or more
57 conferences between a potential applicant and FDA as described in 21 CFR 514.5
58 to reach a binding agreement establishing a submission or investigational
59 requirement.
 - 60 7. The term “dosage characterization” is understood to mean a justification of the
61 dosage (dose or dose range, dosing frequency, and the dosing duration) and a
62 characterization of the critical aspects of the dose-response relationship related to
63 each intended use and associated conditions of use.

64 **I. Performance Goals for Fiscal Year 2014**

65 **Non-administrative Animal Drug Applications**

- 66 1. The Agency will review and act on 90 percent of non-administrative animal drug
67 applications and reactivations of such applications within
 - 68 i. 180 days after the submission date (Day 180) if the Agency determines
69 that the application is complete or incomplete. An application is
70 incomplete if it would require substantial data or information to enable the
71 Agency to complete a comprehensive review of the application and reach
72 a decision on the approvability of the application; or
 - 73 ii. 220 days after the submission date if the Agency determines that the
74 submission of additional non-substantial data or information would likely
75 complete the application and electronically requests an end-review
76 amendment to the application on or before Day 180, but the sponsor fails
77 to file such amendment on or before Day 210. If a sponsor files an
78 amendment after Day 210, then the amendment is ineligible for
79 consideration as an end-review amendment, the extended performance
80 goal (345 days) will not apply, and a complete action letter will be issued
81 by Day 220 for the original application; or
 - 82 iii. 345 days after the submission date if the Agency electronically requests an
83 end-review amendment to the application on or before Day 180 and the
84 sponsor files an end-review amendment on or before Day 210.

- 85 2. The end-review amendment procedure is not intended to prevent the use of minor
86 amendments as described in Definitions, paragraph 2. above during Agency
87 review of a non-administrative animal drug application.

88 **Non-manufacturing Supplemental Animal Drug Applications**

- 89 1. The Agency will review and act on 90 percent of non-manufacturing
90 supplemental animal drug applications (i.e. supplemental animal drug applications
91 for which safety or effectiveness data are required) and reactivations of such
92 supplemental applications within
- 93 i. 180 days after the submission date (Day 180) if the Agency determines
94 that the application is complete or incomplete. An application is
95 incomplete if it would require substantial data or information to enable the
96 Agency to complete a comprehensive review of the application and reach
97 a decision on the approvability of the application; or
 - 98 ii. 220 days after the submission date if the Agency determines that the
99 submission of additional non-substantial data or information would likely
100 complete the application and electronically requests an end-review
101 amendment to the application on or before Day 180, but the sponsor fails
102 to file such amendment on or before Day 210. If a sponsor files an
103 amendment after Day 210, then the amendment is ineligible for
104 consideration as an end-review amendment, the extended performance
105 goal (345 days) will not apply, and a complete action letter will be issued
106 by Day 220 for the original application; or
 - 107 iii. 345 days after the submission date if the Agency electronically requests an
108 end-review amendment to the application on or before Day 180 and the
109 sponsor files an end-review amendment on or before Day 210.
- 110 2. The end-review amendment procedure is not intended to prevent the use of minor
111 amendments during Agency review of a supplemental new animal drug
112 application as described in Definitions, paragraph 2. above.

113 **Investigational Animal Drug Study Submissions**

- 114 1. The Agency will review and act on 90 percent of investigational animal drug
115 study submissions within
- 116 i. 180 days after the submission date (Day 180) if the Agency determines
117 that the submission is complete or incomplete. A submission is
118 incomplete if it would require substantial data or information to enable the
119 Agency to complete a comprehensive review of the study submission and
120 reach a decision on the issue(s) presented in the submission; or
 - 121 ii. 220 days after the submission date if the Agency determines that the
122 submission of additional non-substantial data or information would likely
123 complete the submission and electronically requests an end-review
124 amendment to the submission on or before Day 180, but the sponsor fails
125 to submit such amendment on or before Day 210. If a sponsor submits an
126 amendment after Day 210, then the amendment is ineligible for

- 127 consideration as an end-review amendment, the extended performance
128 goal (270 days) will not apply, and a complete action letter will be issued
129 by Day 220 for the original submission; or
130 iii. 270 days after the submission date if the Agency electronically requests an
131 end-review amendment to the submission on or before Day 180 and the
132 sponsor submits an end-review amendment on or before Day 210.
133 2. The end-review amendment procedure is not intended to prevent the use of minor
134 amendments as described in Definitions, paragraph 2. above during Agency
135 review of a study submission.

136 **Investigational Animal Drug Protocols without Data Submissions**

- 137 1. Review and act on 90 percent of investigational animal drug submissions
138 consisting of protocols without substantial data, that the Agency and the sponsor
139 consider to be an essential part of the basis for making the decision to approve or
140 not approve an animal drug application or supplemental animal drug application,
141 within
142 i. 60 days after the submission date (Day 60) if the Agency does not request
143 an end-review amendment to the protocol.
- 144 (1) If the Agency determines that the protocol is acceptable, the Agency
145 will notify the sponsor of this decision electronically on or before Day 50,
146 followed by a complete action letter; or
- 147 (2) If the Agency determines that a protocol is not acceptable, the Agency
148 will notify the sponsor of this decision electronically, providing
149 preliminary broad areas of protocol deficiency, on or before Day 50, with
150 the subsequently issued complete action letter providing the detailed
151 protocol assessment. The sponsor may contact the Agency for a brief
152 clarification of these areas of deficiency prior to the issuance of the
153 complete action letter; or
- 154 ii. 75 days after the submission date if the Agency electronically requests an
155 end-review amendment to the protocol on or before Day 50, but the
156 sponsor fails to submit such amendment within 10 days of the amendment
157 request date. If a sponsor files an amendment more than 10 days after the
158 amendment request date, then the amendment is ineligible for
159 consideration as an end-review amendment, the extended performance
160 goal (refer to paragraph 1.iii of this section) will not apply, and a complete
161 action letter will be issued by Day 75 for the original submission; or
162 iii. the greater of 60 days after the original protocol is received by the Agency
163 or 20 days after the amended protocol is received by the Agency if the
164 Agency electronically requests an end-review amendment on or before
165 Day 50 and the sponsor submits such amendment within 10 days of the
166 date the amendment is requested.

- 167 2. Sponsors are not required to submit study protocols for review. However, for
168 each voluntarily submitted protocol for a study that the Agency and the sponsor
169 consider to be an essential part of the basis for making the decision to approve or
170 not approve an animal drug application or supplemental animal drug application,
171 the Agency will issue a complete action letter providing comments resulting from
172 a complete review of the protocol. The complete action letter will be as detailed
173 as possible considering the quality and level of detail of the protocol submission;
174 will include a succinct assessment of the protocol; and will state whether the
175 Agency agrees, disagrees, or lacks sufficient information to reach a decision that
176 the protocol design, execution plans, and data analyses are adequate to achieve the
177 objectives of the study.
- 178 3. If the Agency determines that a protocol is acceptable, this represents an
179 agreement that the data generated by the protocol can be used to support a safety
180 or effectiveness decision regarding the subject animal drug. The fundamental
181 agreement is that having agreed to the design, execution, or analyses proposed in
182 protocols reviewed under this process, the Agency will not later alter its
183 perspectives on the issues of design, execution, or analyses unless the Agency by
184 written order determines that a substantiated scientific requirement essential to the
185 assessment of the study appeared after the Agency's protocol assessment, or
186 public or animal health concerns unrecognized at the time of protocol assessment
187 under this process are evident.
- 188 4. The end-review amendment procedure is not intended to prevent the use of minor
189 amendments as described in Definitions, paragraph 2.above during Agency
190 review of a protocol without data submission.

191 **II. Performance Goals for Fiscal Years 2015 – 2018**

192 On October 1, 2014, the beginning of fiscal year 2015, the Agency will discontinue
193 end-review amendment procedures and replace them with a process for shorter
194 review times for reactivations and resubmissions as outlined in the
195 Application/Submission goals section of this letter. These new procedures only apply
196 when the sponsor provides submissions for the NADA and INAD through the use of
197 the eSubmitter electronic submission tool. The original application/submission and
198 the reactivation/resubmission must be submitted through the eSubmitter tool to be
199 eligible to take advantage of the new procedures for the shorter review times for
200 qualified reactivations/resubmissions.

201 **Application/Submission Goals**

202 1. Non-administrative New Animal Drug Applications (NADAs)

203 Review and act on 90 percent of non-administrative NADAs within 180 days after the
204 submission date.

205 An application is incomplete if it would require additional data or information to
206 enable the Agency to complete a comprehensive review of the application and reach a
207 decision on the issue(s) presented in the application.

208 The Agency will review and act on 90 percent of reactivated applications:

- 209 i Within 180 days after the reactivated NADA submission date if the Agency
210 determines and notifies the sponsor that the deficiencies are substantial;
- 211 ii Within 135 days after the reactivated NADA submission date if the Agency
212 determines and notifies the sponsor that the deficiencies are not substantial;
213 and the NADA reactivation must be submitted no more than 120 days after
214 the Agency's dated incomplete letter to qualify for the shorter review time;
215 and
- 216 iii Within 180 days after the reactivated NADA submission date if the NADA
217 reactivation is submitted after 120 days of the Agency's dated incomplete
218 letter or new substantial information is provided in the reactivated application.

219 The Agency will generally favor using the shorter reactivation timeframe of 135 days,
220 where possible. The Agency will state in the incomplete letter the appropriate
221 timeframe for review of the reactivation. Sponsors wishing to discuss the selected
222 timeframe should contact the Agency prior to reactivation of the application. The
223 shorter review time of 135 days for reactivated NADAs for which the deficiencies are
224 determined not to be substantial is not intended to prevent the use of minor
225 amendments during Agency review of an application.

226 2. Non-manufacturing Supplemental Animal Drug Applications

227 The Agency will review and act on 90 percent of non-manufacturing supplemental
228 animal drug applications (i.e. supplemental animal drug applications for which safety
229 or effectiveness data are required) within 180 days after the submission date.

230 A supplemental application is incomplete if it would require additional data or
231 information to enable the Agency to complete a comprehensive review of the
232 supplement and reach a decision on the issue(s) presented in the supplement.

233 The Agency will review and act on 90 percent of reactivated supplements:

- 234 i Within 180 days after the resubmission date if the Agency determines and
235 notifies the sponsor that the deficiencies are substantial.
- 236 ii Within 135 days after the resubmission date if the Agency determines and
237 notifies the sponsor that the deficiencies are not substantial; and the
238 resubmission to the supplemental application must be submitted no more than
239 120 days after the Agency's dated incomplete letter to qualify for the shorter
240 review time; and
- 241 iii Within 180 days after the resubmission date if the resubmission to the
242 supplemental application is submitted after 120 days of the Agency's dated

243 incomplete letter or new substantial information is provided in the
244 resubmission.

245 The Agency will generally favor using the shorter resubmission timeframe of 135
246 days, where possible. The Agency will state in the incomplete letter the appropriate
247 timeframe for review of the reactivation. Sponsors wishing to discuss the selected
248 timeframe should contact the Agency prior to resubmitting the supplement. The
249 shorter review time of 135 days for resubmissions for which the deficiencies are
250 determined not to be substantial is not intended to prevent the use of minor
251 amendments during Agency review of a supplemental application.

252 3. Investigational New Animal Drug (INAD) Study Submissions

253 Review and act on 90 percent of INAD study submissions within 180 days after the
254 submission date.

255 An INAD study submission is incomplete if it would require additional data or
256 information to enable the Agency to complete a comprehensive review of the
257 submission and reach a decision on the issue(s) presented in the submission.

258 The Agency will review and act on 90 percent of resubmissions:

- 259 i Within 180 days after the resubmitted INAD study submission date if the
260 Agency determines and notifies the sponsor that the deficiencies are
261 substantial;
- 262 ii Within 60 days after the resubmitted INAD study submission date if the
263 Agency determines and notifies the sponsor that the deficiencies are not
264 substantial; and the resubmission must be submitted no more than 120 days
265 after the Agency's dated incomplete letter to qualify for the shorter review
266 time; and
- 267 iii Within 180 days after the resubmitted INAD study submission date if the
268 resubmission is submitted after 120 days of the Agency's dated incomplete
269 letter or new substantial information is provided in the resubmission.

270 The Agency will generally favor using the shorter resubmission timeframe of 60
271 days, where possible. The Agency will state in the incomplete letter the appropriate
272 timeframe for review of the reactivation. Sponsors wishing to discuss the selected
273 timeframe should contact the Agency prior to resubmitting the application. The
274 shorter review time of 60 days for resubmissions for which the deficiencies are
275 determined not to be substantial is not intended to prevent the use of minor
276 amendments during Agency review of a submission.

277 Review and act on 90 percent of microbial food safety hazard characterization
278 submissions within 100 days after the submission date.

279 4. INAD Protocols without Data Submissions

280 Review and act on 90 percent of INAD submissions consisting of protocols without
281 data, that the Agency and the sponsor consider to be an essential part of the basis for
282 making the decision to approve or not approve an animal drug application or
283 supplemental animal drug application, within 50 days after the submission date.

284 An INAD protocol without data submission is incomplete if it would require
285 additional information to enable the Agency to complete a comprehensive review of
286 the protocol and reach a decision on the issue(s) presented in the protocol.

287 The Agency will review and act on 90 percent of resubmitted INAD protocol without
288 data submissions:

- 289 i Within 50 days after the resubmission date if the Agency determines and
290 notifies the sponsor that the deficiencies are substantial;
- 291 ii Within 20 days after the resubmitted INAD protocol without data submission
292 date if the Agency determines and notifies the sponsor that the deficiencies are
293 not substantial; and the resubmission must be submitted no more than 120
294 days after the Agency's dated non-concurrence letter to qualify for the shorter
295 review time; and
- 296 iii Within 50 days after the resubmission date if the resubmission is submitted
297 after 120 days of the Agency's dated non-concurrence letter or new
298 substantial information is provided in the resubmission.

299 The Agency will generally favor using the shorter resubmission timeframe of 20
300 days, where possible. The Agency will state in the non-concurrence letter the
301 appropriate timeframe for review of the resubmission. Sponsors wishing to discuss
302 the selected timeframe should contact the Agency prior to resubmission of the
303 protocol without data. The shorter review time of 20 days for resubmitted INAD
304 protocol without data submissions for which the deficiencies are determined not to be
305 substantial is not intended to prevent the use of minor amendments during Agency
306 review of a submission.

307 Sponsors are not required to submit study protocols for review. However, for each
308 voluntarily submitted protocol for a study that the Agency and the sponsor consider to
309 be an essential part of the basis for making the decision to approve or not approve an
310 animal drug application or supplemental animal drug application, the Agency will
311 issue a complete action letter providing comments resulting from a complete review
312 of the protocol. The complete action letter will be as detailed as possible considering
313 the quality and level of detail of the protocol submission; will include a succinct
314 assessment of the protocol; and will state whether the Agency agrees, disagrees, or
315 lacks sufficient information to reach a decision that the protocol design, execution
316 plans, and data analyses are adequate to achieve the objectives of the study.

317 If the Agency determines that a protocol is acceptable, this represents an agreement
318 that the data generated by the protocol can be used to support a safety or effectiveness
319 decision regarding the subject animal drug. The fundamental agreement is that

320 having agreed to the design, execution, or analyses proposed in protocols reviewed
321 under this process, the Agency will not later alter its perspectives on the issues of
322 design, execution, or analyses unless the Agency by written order determines that a
323 substantiated scientific requirement essential to the assessment of the study appeared
324 after the Agency's protocol assessment, or public or animal health concerns
325 unrecognized at the time of protocol assessment under this process are evident.

326 5. Labeling Supplements

327 Review and act on 90 percent of qualifying labeling supplements as described in 21
328 CFR 514.8(c)(2)(i)(A) and (D) within 60 days after the submission date. Qualifying
329 labeling supplements are defined as those submitted through the use of the eSubmitter
330 electronic submission tool, for which the sponsor provides and certifies a complete
331 list of label changes made in the application and that CVM can determine upon initial
332 review do not decrease the safety of drug use.

333 The Agency will review and act on 90 percent of non-qualifying labeling supplements
334 within 180 days after the submission date.

335 **III. Performance Goals for Fiscal Years 2014 – 2018**

336 **Work Queue Review Procedures**

337 The Agency will review all submissions in accordance with procedures for working
338 within a queue. An application/submission that is not reviewed within the applicable
339 Application/Submission Goal time frame (noted above) will be reviewed with the highest
340 possible priority among those pending.

341 **Timely Meetings with Industry**

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

346 **Administrative NADAs**

347 Review and act on 90 percent of administrative NADAs (NADAs submitted after all
348 scientific decisions have been made in the investigational new animal drug process, i.e.,
349 prior to the submission of the NADA) within 60 days after the submission date.

350 **Manufacturing Supplemental Animal Drug Applications**

351 Review and act on 90 percent of manufacturing supplemental animal drug applications
352 within 120 days after the submission date.

353 A submission is incomplete if it would require additional data or information to enable
354 the Agency to complete a comprehensive review of the submission and reach a decision
355 on the issue(s) presented in the submission. If the Agency determines and notifies the
356 sponsor that the deficiencies are not substantial for manufacturing supplements requiring
357 prior approval according to 21 CFR 514.8(b), the Agency will permit the manufacturing
358 supplements to be resubmitted as “Supplement-Changes Being Effected in 30 Days” as
359 described in 21 CFR 514.8(b)(3). The Agency will generally favor permitting prior
360 approval supplements to be resubmitted as “Supplement-Changes Being Effected in 30
361 Days”, where possible. The Agency will state in the incomplete letter whether the
362 reactivation can be submitted as a “Supplement-Changes Being Effected in 30 Days”. If
363 the Agency determines and notifies the sponsor that the deficiencies are substantial or
364 new substantial information is provided in the resubmission, the Agency will review and
365 act on 90 percent of reactivated manufacturing supplements within 120 days after the
366 resubmission date.

367 **Comparability Protocols**

368 Permit comparability protocols as described in 21 CFR 514.8(b)(2)(v) to be submitted as
369 protocols without substantial data in a INAD file. The Agency will review and act on 90
370 percent of INAD submissions consisting of protocols without substantial data within 50
371 days after the submission date of the protocol. For potentially more complex
372 comparability protocols, for example sterile process validation protocols, the sponsor
373 should discuss and have Agency concurrence regarding the appropriate filing strategy.

374 **Multiple Data Submissions to the Chemistry Manufacturing Controls Technical** 375 **Section**

376 The Agency will develop guidance for a two-phased Chemistry, Manufacturing and
377 Controls (CMC) technical section submission and review process under the INAD file by
378 the end of fiscal year 2014. If sponsors are interested in using a two-phased submission
379 and review process for the CMC technical section before the draft guidance document is
380 issued, they can contact the Agency.

381 **Pre-Approval Foreign Inspections**

382 1. The Agency and regulated industry are committed to improving the review and
383 business processes that will facilitate the timely scheduling and conducting of pre-
384 approval inspections (PAIs). To improve the timeliness and predictability of
385 foreign PAIs, sponsors may voluntarily submit 1) at the beginning of the calendar
386 year, a list of foreign manufacturing facilities that are specified in an animal drug
387 application, supplemental animal drug application, or investigational animal drug
388 submission and may be subject to foreign PAIs for the following fiscal year; and
389 2) a notification 30 days prior to submitting an animal drug application, a
390 supplemental animal drug application, or investigational animal drug submission
391 that informs the Agency that the application includes a foreign manufacturing

392 facility. Should any changes to the annual list occur after its submission to the
393 Agency, the sponsor may provide the updated information to the Agency.
394 2. The Agency will keep a record of the number of foreign PAIs conducted for new
395 animal drug applications, along with the average time for completing the PAIs,
396 and include this information in its annual performance report. The time for
397 completing the PAI is understood to mean the time from the inspection scheduling
398 request through notification to the Center of inspectional findings.

399 **Supporting Information for Presubmission Conferences and INAD Protocols**
400 **without data submissions**

401 The Agency and the regulated industry agree that data and/or information which uniquely
402 describes the general attributes of the new animal drug (e.g. the known characteristics of
403 the drug that can impact safety, effectiveness and/or quality) needs to be submitted early
404 in the new animal drug development process in order to enable the parties to reach
405 agreement at a presubmission conference or to begin review of a protocol. The intent of
406 this provision is to avoid the submission of data or information between the
407 presubmission conference and the submission of a protocol. Eligibility both for short
408 justifications in protocols and for concurrent supporting data and protocol review
409 described below is predicated on the sponsor submitting information early in the new
410 animal drug development process.

411 The Agency will allow for the inclusion of this data and/or information in presubmission
412 conferences, however it would not preclude holding a presubmission conference without
413 such data. Presubmission conferences will be held approximately 100 days after the
414 submission of the data supporting the request.

415 The Agency will allow short justifications within INAD protocols without data
416 submissions that are limited in scope (e.g., no more than ten pages or no more than two
417 (peer-reviewed) journal articles).

418 The Agency will allow for the concurrent submission of supporting data (INAD H
419 submissions) and protocols (INAD E submissions) provided that the protocol is not
420 submitted until the supporting data has been in the Agency's queue for at least 50 days.

421 **Dosage Characterization**

422 The Agency and the regulated industry agree that dosage characterization is part of the
423 effectiveness technical section of an investigational new animal drug file. In instances
424 where data and/or information about the dosage is integral to the review of a protocol, the
425 Agency and the regulated industry agree that this data and/or information should be
426 submitted as supporting data (INAD H submission) well in advance of the protocol
427 submission. Such information may be needed to ensure selection of optimal study time
428 points and would be particularly important for novel drugs and drugs with modified-
429 release characteristics.

430 **Conditional Approval**

431 Beginning in early FY 2014, the Agency agrees to explore, in concert with industry, the
432 feasibility of pursuing statutory revisions, consistent with the Agency's mission to protect
433 and promote the public health, that may expand the use of conditional approvals to other
434 appropriate categories of new animal drug applications and develop recommendations by
435 September 30, 2015.

436 **ADAA Combinations**

437 Beginning in early FY 2014, the Agency agrees to explore, in concert with affected
438 parties, the feasibility of pursuing statutory revisions, consistent with the Agency's
439 mission to protect and promote the public health, that may modify the current
440 requirement that the use of multiple new animal drugs in the same medicated feed be
441 subject to an approved application and develop recommendations by September 30, 2016.

442 **Workload Adjustment**

443 The proposed amendment to the Animal Drug User Fee Act of 2003, as amended in
444 2008, requires FDA to annually adjust fee revenues after fiscal year 2014 to reflect
445 changes in review workload utilizing a weighted average of the change in the total
446 number of applications for new animal drugs, non-manufacturing supplemental animal
447 drug applications (i.e. supplemental animal drug applications for which safety or
448 effectiveness data are required), manufacturing supplemental applications for new animal
449 drugs, investigational new animal drug study submissions, and investigational new
450 animal drug protocol submissions. The Agency will use the method detailed below to
451 calculate the workload adjustment, and the percent increase in fees will be made if the
452 amount of the workload adjuster is equal to or greater than one percent (1%). In
453 accordance with the statute, the workload adjustment will not result in fee revenues for a
454 fiscal year that are less than the fee revenues for that fiscal year as specified in the statute.

455 The term "workload adjuster" applicable to a fiscal year consists of the sum of the
456 percent of change in the total number of each of the five component submission types
457 submitted (comparing the five-year average number of such submissions for fiscal years
458 2009 – 2013 -- the base years -- to the five-year average for the most recent five-year
459 period ending June 30 before the start of the next fiscal year) times a weighting factor
460 that is the percent of direct review time spent on the each of the five component
461 submission types over the most recent five-year period.