

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

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90 I. Introduction and Background

91
92 This draft document contains the performance goals and procedures for the Over-the-Counter
93 Monograph Drug User Fee Act initial program. If the program is enacted by Congress, the
94 program will likely subsequently be abbreviated OMUFA. For simplicity, the program will
95 generally be abbreviated as OMUFA in the remainder of this document. The over-the-counter
96 drug monograph will generally be referred to simply as the monograph. The document assumes
97 that the effective date of the OMUFA program will be October 1, 2017, and that it will cover
98 fiscal years (FYs) 2018-2022. If the program has a different effective date, goal dates in this
99 document will need to be adjusted accordingly.

100
101 For user fee programs, this type of document is commonly referred to as the “goals letter” or
102 “commitment letter.” This goals document represents the product of FDA’s discussions with
103 the regulated Industry, and consideration of input by public stakeholders.

104
105 OMUFA discussions ensued from prior discussions of the need for extensive policy reforms in
106 order to preserve and modernize the over-the-counter drug monograph regulatory system.
107 These reforms, if enacted by Congress, will result in numerous positive benefits to the public
108 health, and to regulated Industry. The United States Food and Drug Administration (hereafter
109 generally referred to as FDA) and regulated Industry have also come to agreement on the
110 principles of a system of monograph user fees through which regulated Industry will provide
111 resources to enable the range of review activities necessary to meet the goals of the
112 monograph reform.

113
114 The performance and procedural goals and other commitments specified in this letter apply to
115 aspects of the over-the-counter monograph drug review program that are important for
116 facilitating timely access to safe and effective medicines regulated under the over-the-counter
117 drug monograph, and to implementing the aforementioned policy reforms. While much of
118 FDA’s work is associated with formal tracked performance goals, FDA and Industry mutually
119 agree that it is appropriate to manage some areas of the human drug review program with
120 internally tracked timeframes. This provides FDA the flexibility needed to respond to a highly
121 diverse workload, including unanticipated public health needs. FDA is committed to meeting
122 the performance goals specified in this goals document and to continuous improvement of its
123 performance. FDA and the regulated Industry will periodically assess the progress of the over-
124 the-counter drug monograph review program. This will allow FDA and the regulated Industry to
125 identify emerging challenges and develop strategies to address these challenges to ensure the
126 efficiency and effectiveness of the over-the-counter monograph drug review program.

127
128 Many aspects of this goals document will be addressed in statutory language. If differences are
129 noted between the OMUFA goals document and statutory language, statutory language will
130 supersede this goals document.

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II. Goals for the First Cycle of an Over-the-Counter Monograph User Fee Program

It should be noted that, when there are very few instances of a given activity, adherence to performance goals should be interpreted accordingly. For example, if there are so few occurrences of an activity that missing only one or two goal dates would make it appear that the performance goal was not met, a qualitative description of performance may provide more useful data to be used in improving future performance.

A. Building the Basic Infrastructure to Enable the Goals of Monograph Reform to be Met

1. Hiring

The FDA will target onboarding of the following numbers of new fulltime employee equivalents (FTEs) in each of the fiscal years (FYs) specified below.

Hiring Onboarding Targets:

FY 2018: 30
FY 2019: 24
FY 2020: 23
FY 2021: 19
FY 2022: 9

2. Training and Growth of Effective Review Capacity

FDA will work toward the above hiring goals, but it is important to note that, although new scientific reviewers begin review work immediately, new reviewers will not be fully effective immediately as scientific reviewers, and that effective review capacity will grow slowly at first. FDA scientific review work is highly technical and specialized, requiring knowledge and skills that must be taught after onboarding. Typically, two years are required for a scientific reviewer to take all the necessary training, and acquire all the knowledge and experience needed to be fully effective. This training process occurs simultaneously with assigned review work, with increasing review workload as a new reviewer gains experience and training.

Immediately prior to OMUFA, FDA expects to have approximately 35 FTE working on monograph issues, only 18 of whom work fulltime in the relevant review division. A total of 29 of these 35 FTE are expected to be fully trained at the time OMUFA becomes effective, and 6 are expected to be recent hires who are still training. Given this fact, and the time required for

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171 training of additional hires under OMUFA, and the above hiring numbers, effective review
172 capacity is expected to grow as follows:

173

174 Mean Effective Monograph Review Capacity, FYs 2018-22:

175

176 FY 2018: 31 FTE

177 FY 2019: 42 FTE

178 FY 2020: 64 FTE

179 FY 2021: 88 FTE

180 FY 2022: 110 FTE

181

182 This concept is important, because it illustrates that during the early years of OMUFA, although
183 FDA will be striving to meet onboarding targets, FDA will actually not begin to see significant
184 growth in effective review capacity until FY 2020. Also of note is the fact that although hiring is
185 to be complete by the end of FY 2022, growth in review capacity will continue beyond the end
186 of FY 2022 as employees hired in FYs 2021 and 2022 continue and complete their training in the
187 ensuing years.

188

189 During FYs 2015, 2016, and 2017 (which began October 1, 2016), essentially all of FDA's current
190 monograph review capacity has been consumed by the following three activities:

- 191 • Statutory requirements of the Sunscreen Innovation Act
- 192 • Court-mandated requirements of the antiseptic consent decree
- 193 • Pressing safety activities

194

195 During FYs 2018 and 2019, FDA will continue to have mandated obligations under the antiseptic
196 consent decree. As of the writing of this goals document, mandated obligations also continue
197 under the Sunscreen Innovation Act during those years (and perhaps subsequent years as well),
198 unless Congress chooses to change that law. Safety activities, for both pressing issues and
199 routine pharmacovigilance, are continuous at FDA.

200

201 In addition, during the first three years of OMUFA, numerous activities will need to occur to put
202 the necessary infrastructure into place, and to begin to implement the various aspects of the
203 proposed monograph reforms. Examples of these activities include:

- 204 • Leadership development (particularly important when beginning from such a small
205 initial staff knowledgeable in the monograph)
- 206 • Information technology (IT) platform development and implementation (no IT platform
207 exists for the monograph prior to OMUFA)
- 208 • Development and posting of a nonbinding list of forecasted monograph activities (see
209 Section II.C.2)
- 210 • Activities to reflect finalization of Category I ingredients from Tentative Final
211 Monograph (TFM) status to Generally Recognized as Safe and Effective (GRASE)

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- 212 • For TFM Category II ingredients, which will be deemed not GRASE (not Generally
213 Recognized as Safe and Effective) at time of enactment, Industry requestors may elect
214 to submit requests to submit data packages supporting the safety and/or efficacy of
215 these ingredients. FDA resources will be required to consider these requests.
- 216 • User fee collection system implementation and collection activities

217
218 Resource estimates indicate that, in order to implement all these activities and continue
219 externally mandated activities, FDA will be substantially “net-negative” in terms of effective
220 review capacity for the first 3 years of OMUFA. There will be performance goals for
221 implementation activities such as development of guidances and hiring in the first three years.
222 By Year 3, review resources will grow to the point where limited performance goals can begin
223 for meetings. In Years 4 and 5, FDA expects to be able to implement timelines and limited
224 performance goals for OMOR submissions, and will continue progressive performance goals for
225 meeting management, guidance development, and other activities, although FDA’s effective
226 monograph review capacity will still not be expected to be at the steady state required to
227 handle the eventual anticipated full workload of OMUFA activities. Training will continue, with
228 expected continued growth of review capacity beyond the first five years of OMUFA as all
229 hires finish their training and reach full review capability.

230
231 After establishment of the necessary infrastructure, and based on estimates of review activity
232 expected numbers provided by Industry, FDA expects that the FTE need for monograph
233 activities at steady state will be the equivalent of approximately 140 FTE. The steady state
234 estimate includes those activities that are expected to be part of a continuing program over
235 time, and does not include activities that are only part of start-up and implementation. Some
236 examples of activities expected to occur at steady state include:

- 237 • Industry-requested Over-the-Counter Monograph Order Requests (OMORs) for
238 innovations and other changes to the monograph
- 239 • Industry-requested guidances for innovations (and administrative orders that will
240 accompany these guidances)
- 241 • Industry-requested meetings with FDA
- 242 • Industry-requested dispute resolution, up to the Center for Drug Evaluation and
243 Research (CDER) level, and above CDER under a new administrative hearing procedure
- 244 • Industry-requested finalizations of GRASE determinations for nonfinal monograph
245 ingredients and other monograph conditions of use
- 246 • Industry-requested safety changes to monograph drug labeling
- 247 • Industry resubmissions of OMORs for which a previous final order did not result in the
248 requested change to the monograph
- 249 • FDA-requested safety changes to monograph drug labeling
- 250 • FDA-requested packages for GRASE determinations
- 251 • Other monograph review activities

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- 252 • Other guidance and policy development
- 253 • Information technology support
- 254 • Reporting
- 255 • User fee management
- 256 • Other activities specified in the OMuFA statute

257

258 In summary, during the first three years of OMuFA, essentially all effective review capacity is
259 expected to be consumed by current external mandates, safety activities, and OMuFA
260 implementation and infrastructure development activities. Beginning in Years 4 and 5 (and to a
261 limited extent in Year 3), FDA expects to have built sufficient effective review capacity to begin
262 to have timelines and performance goals for review activities expected to be part of the steady
263 state of a monograph review program.

264

265 3. Development and Implementation of an Information Technology Platform

266

267 Prior to OMuFA, no IT platform exists for the monograph, a lack which greatly hampers review
268 efficiency.

269

270 a. Development of the Information Technology Platform

271

272 FDA will develop specifications for a public-facing IT dashboard and award a contract by
273 October 1, 2018.

274

275 FDA will implement the above public-facing IT dashboard by October 1, 2019.

276

277 FDA will issue a Request for Proposals for an information technology (IT) platform for receiving
278 electronic submissions, archiving review work, and generating reports, for over-the-counter
279 (OTC) drug monograph review, by February 1, 2019.

280

281 FDA will award the initial contracts for the above IT platform by April 1, 2019.

282

283 FDA will establish business requirements for the above IT platform by April 1, 2020.

284

285 FDA will establish a fully functioning IT platform for OTC drug monograph review by April 1,
286 2022.

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292 b. Electronic Submissions

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294 In order to maximize the efficiency of the monograph review process, all monograph
295 submissions from industry are to be electronic rather than paper. Industry may submit
296 monograph electronic submissions to FDA starting on October 1, 2017.

297

298 FDA will provide additional information regarding electronic submissions for the monograph in
299 draft guidance to be issued by October 1, 2019. FDA will issue final guidance for electronic
300 submissions for the monograph by April 1, 2021.

301

302 c. Content and Format of Monograph Submissions

303

304 Initially (beginning October 1, 2017), Over-the-Counter Monograph Order Requests (OMORs)
305 are to be submitted using content and format recommendations described in the guidance for
306 Industry *Nonprescription Sunscreen Drug Products – Content and Format of Data Submissions*.
307 The format recommendations of this guidance, although developed for sunscreen drug
308 products, are generally applicable to all monograph submissions.

309

310 FDA will modify the above content and format guidance to clarify its applicability across
311 monograph drug products. FDA will issue updated draft guidance by April 1, 2019. FDA will
312 issue final guidance by October 1, 2020.

313

314 OMORs are expected to be complete at the time of submission, and are expected to include all
315 information, both positive and negative, relevant to the determination of general recognition of
316 safety and effectiveness for the ingredient or other condition(s) of use under consideration.
317 OMOR requestors are required to submit a certification that the requestor has submitted all
318 evidence created, obtained, or received by that requestor that is relevant to whether the
319 ingredient or other condition of use is generally recognized as safe and effective (GRASE).

320

321 d. Cataloging of Pre-OMUFA Paper Documents

322

323 Some paper documents that reside with FDA contain information of importance relating to
324 monograph ingredients and their review. Prior to OMUFA, FDA has not had the resources to
325 catalog and archive these documents. Many of these documents are old and fragile. It is
326 important to catalog the content of these documents, and FDA must retain paper documents as
327 required by established records retention policies. Because of the large volume of these
328 documents, and the fragility of many of them, the process of sorting, scanning, and archiving
329 them would be costly and time-consuming. Industry does not support provision of user fee
330 funds to permit electronic archiving of these documents during the first five years of OMUFA,
331 but agrees that cataloging them could have value to Industry, because some of the documents
332 may contain data that Industry requestors could use to support order requests or other
333 activities of interest to Industry. FDA and Industry have agreed that, among IT-related goals, the

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334 priority of creating the IT platform is higher than that of cataloging these paper documents, and
335 therefore IT platform development would be pursued first. Cataloging will have a limited goal of
336 identifying the monograph ingredient(s) discussed in each document, and creation of a
337 searchable electronic catalog. Cataloged paper documents will be stored per records retention
338 policies, but the paper documents themselves will not be scanned and electronically archived.
339 By February 3, 2020, FDA will award a contract for the cataloging project. By Feb 3, 2022, the
340 cataloging project will be complete. FDA will be able to initiate GRASE determinations prior to
341 completion of the cataloging project.

342

343 B. Enabling Industry-Initiated Innovation

344

345 1. Over-the-Counter Monograph Order Requests (OMORs) for Innovations

346

347 Prior to the proposed monograph reforms, innovation under the monograph has been difficult.
348 Under monograph reform, sponsors (hereafter referred to as requestors when referencing
349 submission of OMORs) will be able to submit data packages (Over-the-Counter Monograph
350 Order Requests, or OMORs) to FDA, with requests that FDA issue an administrative order for a
351 change to a monograph. Hereafter, these packages requesting changes to monographs will be
352 referred to as "Innovation OMORs."

353

354 a. Tier One and Tier Two Innovation OMORs

355

356 There will be two types of Innovation OMORs, referred to as Tier One Innovation OMORs and
357 Tier Two Innovation OMORs.

358

359 Most Innovation OMORs will be Tier One OMORs. Examples include, but are not limited to,
360 requests for the following:

- 361 • Addition of a new ingredient to a monograph that already has one or more ingredients
362 that have been found to be GRASE
- 363 • Addition of a new indication to a monograph that already has one or more ingredients
364 that have been found to be GRASE, and the new indication applies to one or more of the
365 GRASE ingredients
- 366 • Addition of a new fixed-dose combination of ingredients to a monograph that already
367 has one or more ingredients that have been found to be GRASE
- 368 • Addition of a new test method for a monograph that already has one or more
369 ingredients that have been found to be GRASE, and the new test method applies to one
370 or more of the GRASE ingredients
- 371 • Addition of a new route of administration for a monograph that already has one or
372 more ingredients that have been found to be GRASE, and the new route of
373 administration applies to one or more of the GRASE ingredients

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- 374 • Addition of a new dose or concentration for a GRASE ingredient for a particular
- 375 monograph
- 376 • Addition of a new monograph therapeutic category (each ingredient proposed for the
- 377 new therapeutic category will be a separate OMOR)
- 378 • All other Innovation OMORs not covered in Tier Two

379

380 Tier Two Innovation OMORs will be limited to requests for the following:

- 381 • Reordering of existing information in the Drug Facts label (DFL)
- 382 • Standardization of the concentration or dose of a specific finalized ingredient within a
- 383 particular finalized monograph
- 384 • An ingredient nomenclature change to align with nomenclature of a standards-setting
- 385 organization
- 386 • Addition of an interchangeable term under 21 CFR 330.1(i)
- 387 • Modification to existing DFL Directions for Use, in order to be consistent with a final
- 388 order/guidance pair on minor dosage form changes (see Section II.B.2)
- 389 • Addition of information (either required or optional) to be included under the “Other
- 390 Information” section of Drug Facts labeling, as limited by 21 CFR 201.66(c)(7)
- 391 • Other specific items may be added by FDA later as FDA gains experience with Tier Two
- 392 OMORs

393

394 The decision regarding whether a proposed Innovation OMOR meets one of the above criteria

395 for a Tier Two OMOR will be made by the review division after receipt of the OMOR.

396

- 397 b. Innovations May Only be Made to Ingredients that have had a Final Determination of
- 398 “Generally Recognized as Safe and Effective”

399

400 Innovations may only be made to ingredients that have had a final determination of “Generally

401 Recognized as Safe and Effective”, or GRASE. Under monograph reform, ingredients that are

402 GRASE are limited to the following:

- 403 • Ingredients that were GRASE in a Final Monograph at the time of enactment of
- 404 monograph reform
- 405 • Ingredients that, immediately prior to monograph reform, were proposed as Category I
- 406 in a Tentative Final Monograph
- 407 • Ingredients that have been found GRASE in a final order after enactment of monograph
- 408 reform

409

410 All other ingredients will require a final GRASE determination, with finalization of all relevant

411 monograph conditions of use for that ingredient for a particular therapeutic use, in order for

412 FDA to consider an Innovation OMOR relevant to that ingredient. Examples of these types of

413 ingredients that would require GRASE finalization include, but are not limited to:

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- 414 • Ingredients that, immediately prior to monograph reform, were Category III in a
415 Tentative Final Monograph
- 416 • Ingredients that, immediately prior to monograph reform, were proposed Category I in
417 an Advance Notice of Proposed Rulemaking
- 418 • Other ingredients that have not had a final GRASE determination
419

420 Ideally, if a requestor wants to request a change for an ingredient for which a final GRASE
421 determination has not been made, the requestor would submit an OMOR for the final GRASE
422 determination for the ingredient and all of the relevant monograph conditions of use first, and
423 would submit the Innovation OMOR after FDA issues its final order regarding the GRASE
424 determination for the ingredient. However, a requestor may submit a single OMOR package
425 that contains both the complete data necessary for final GRASE determination for that
426 ingredient and all its relevant conditions of use (referred to as a GRASE Finalization OMOR), and
427 the complete data to support the proposed innovation. Cosubmission of a GRASE Finalization
428 OMOR with an Innovation OMOR will extend the GRASE Finalization OMOR timeline from
429 receipt to issuance of the proposed order by six months, with a consequent extension of the
430 total GRASE Finalization OMOR timeline to final order by six months. If a requestor submits a
431 GRASE finalization OMOR, and later submits an Innovation OMOR before the final order for the
432 relevant GRASE finalization OMOR, the timeline of the subsequently submitted Innovation
433 OMOR will be extended by six months.

434 435 c. OMOR Packages Expected to be Complete at Time of Submission 436

437 OMOR packages are expected to be complete at the time of submission, and FDA will make a
438 determination of whether each package is acceptable for filing. As described in Section II.A.3.c,
439 FDA will issue guidance regarding the content and format of OMOR packages. OMOR
440 requestors are strongly encouraged to request and attend a presubmission meeting (as
441 described in Section II.C.1) for their proposed OMOR, to discuss the expected content, format,
442 and tier for a particular OMOR.

443 444 d. Timelines 445

446 The following table outlines the timelines for Innovation OMOR review, i.e. review of Industry-
447 requested changes to finalized monographs, other than Drug Facts label (DFL) specified safety
448 changes as outlined in Section II.D.

449
450 Currently, prior to enactment of proposed monograph reforms, it takes many years to make a
451 change to a monograph, and the goal under monograph reform is to shorten that timeframe
452 substantially, while still maintaining public comment between proposed and final orders, and
453 maintaining FDA's standards for safety and efficacy. These substantially shortened timeframes
454 are reflected in Table II.B.1.d.

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455
456 Eligibility determination for a new ingredient (a pre-OMOR activity):
457

458 Innovation OMORs for new ingredients will require an eligibility determination. Industry may
459 submit a request for ingredient eligibility determination well in advance of submission of the
460 OMOR. Minimum advance submission periods for eligibility determination requests are
461 specified in the following paragraphs.
462

463 If the ingredient is currently marketed for the same Use in a drug product under a US OTC NDA,
464 and the US OTC NDA drug product has documented sales of over 1 million units, the requestor
465 will submit the eligibility determination request at least 60 calendar days in advance of the
466 OMOR submission. For US OTC NDA products that meet these specific requirements, FDA will
467 issue an eligibility determination by 30 calendar days after receipt of the ingredient eligibility
468 determination request.
469

470 For any ingredient eligibility determination request that does not meet the specific
471 requirements in the immediately preceding paragraph, but that the requestor believes meets
472 eligibility requirements as stated in the applicable statute, the requestor will submit the
473 eligibility determination request at least 120 calendar days in advance of the OMOR
474 submission. For these other types of ingredient eligibility determination requests, FDA will issue
475 an eligibility determination by 90 calendar days after receipt of the eligibility determination
476 request.
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Table II.B.1.d: Timelines for Innovation OMORs (Industry-Initiated Over-the-Counter Monograph Order Requests OMORs for Monograph Changes)			
	Tier One Innovation: Eligible¹ New Ingredient	Tier One Innovation: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other² Monograph Change	Tier Two Innovation
Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 10 months after receipt of OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness³ of comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance⁴ of final order	17.5 months after receipt of OMOR	17.5 months after receipt of OMOR	15.5 months after receipt of OMOR
<p>Abbreviations: OMOR = Over-the-Counter Monograph Order Request</p> <p>1 Eligibility determinations will be required for proposals for the addition of new ingredients to a monograph, but not for changes to other monograph conditions of use for a finalized monograph. See paragraphs immediately preceding this table.</p> <p>2 This includes all proposed changes to the monograph, except for safety changes described in Section II.D, the addition of new ingredients, Tier Two Innovation OMORs, and specific changes for which FDA has issued a final guidance stating that an OMOR is not required (see Section II.B.2).</p> <p>3 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review.</p> <p>4 If comments received are numerous or substantive, there will be a Comment Review Extension of the final order goal date. For Tier One Innovations, the extension will be 5 months; and for Tier Two Innovations, the extension will be 3 months.</p>			

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e. Comment Review Extension

If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date. For Tier One Innovations, the extension will be 5 months; and for Tier Two Innovations, the extension will be 3 months. This extension will be additive to those generated by any major amendment(s).

f. Performance Goals

The first year in which Innovation OMORs will be associated with timelines and performance goals will be Year 4 of OMUFA (Innovation OMORs received on or after October 1, 2020.)

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507 For Innovation OMOR submissions, the following performance goals will apply:

- 508 • Year 4: For 50% of OMOR submissions received in Year 4, FDA will issue a final order by
509 the specified goal date
- 510 • Year 5: For 75% of OMOR submissions received in Year 5, FDA will issue a final order by
511 the specified goal date

512

513 Although there will not be timelines and performance goals associated with Innovation OMORs
514 submitted in Years 1-3, requestors may still submit Innovation OMORs in Years 1-3. If resources
515 permit, FDA intends to review these early OMORs in order of receipt, but timelines and
516 performance goals will not apply.

517

518 g. Assumptions Regarding Expected Numbers of Innovation OMORs in First Five Years of
519 OMuFA

520

521 The assumptions for the first OMuFA cycle were that there would be no Innovation OMORs
522 submitted by Industry over the first 3 years of OMuFA, that 5 Innovation OMORs would be
523 submitted in Year 4, and that 10 Innovation OMORs would be submitted in Year 5.

524

525 h. Major Amendments

526

527 OMORs are expected to be complete at the time of submission, and therefore, unsolicited
528 amendments are expected to be rare. (Unsolicited amendments are amendments other than
529 those submitted in response to a specific FDA information request.) Major amendments
530 (whether solicited or unsolicited) submitted by the original requestor prior to issuance of the
531 proposed order may extend the time to issuance of the proposed order by three months, and
532 consequently may extend the final goal date by three months. Major amendments submitted
533 by the original requestor after the end of the comment period and prior to issuance of a final
534 order may also extend the final goal date by three months. Major amendments may apply to
535 Innovation OMORs, Industry-initiated requests for GRASE finalizations (as discussed in Section
536 II.F), and Industry-initiated requests for certain safety changes to the monograph (as described
537 in Section II.D).

538

539 A major amendment may include, for example:

- 540 • a major clinical safety or efficacy study that was not previously submitted to the current
541 OMOR
- 542 • a major reanalysis of a study or studies previously submitted to the current OMOR

543

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547 i. In-Review Meeting

548

549 For filed Innovation OMORs and for filed Industry-requested GRASE Finalization OMORs, FDA
550 will schedule an in-review meeting to be held between the requestor of the OMOR and FDA.
551 This meeting will generally be held between 8 and 9 months after receipt of the OMOR. The
552 OMOR requestor may request that the meeting be held either face-to-face or via
553 teleconference.

554

555 FDA representatives at the in-review meeting are expected to include:

- 556 • The signatory authority for the OMOR review
- 557 • Discipline review team representatives from discipline areas for which substantive
558 issues in the OMOR have been noted to date

559

560 Not less than 12 calendar days prior to the scheduled in-review meeting, FDA will send a
561 premeeting document to the requestor. The premeeting document will include an agenda, a
562 brief list of substantive issues noted to date, and a brief description of information requests
563 that FDA will ask of the requestor. The total length of the premeeting document generally will
564 not exceed three pages.

565

566 Potential topics for discussion at the in-review meeting include:

- 567 • Substantive issues identified to date
- 568 • Information requests from the review team to the requestor
- 569 • Additional data or analyses the requestor may wish to submit

570

571 Review of the OMOR will not be complete at the time of the in-review meeting, and thus
572 definitive information regarding the content of the future proposed order will not be discussed.

573

574 j. Resubmitted Original OMORs

575

576 A resubmitted original OMOR is an OMOR resubmitted after FDA has issued a Final Order
577 declining to make the requested change to the monograph. The resubmitted OMOR must
578 address all of the deficiencies noted in the final order. A resubmitted OMOR pertains only to
579 the monograph changes requested in the original OMOR; if new changes are requested, a new
580 OMOR is required.

581

582 There will be two classes of resubmitted original OMORs: Class One and Class Two.

583

584

585

586

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587 Class One resubmitted original OMORs are limited to the following items, or combinations of
588 these specified items:

- 589 • Draft or final labeling
- 590 • Safety updates submitted in the same format, including tabulations, as the original
591 safety submission, with new data and changes highlighted. (However, resubmissions
592 with large amounts of new information including important new adverse experiences
593 not previously reported for the ingredient(s) will be Class Two resubmissions.)
- 594 • Assay validation data
- 595 • A minor reanalysis of data previously submitted to the OMOR
- 596 • Other minor clarifying information (determined by the FDA as fitting the Class One
597 category)
- 598 • Other specific items may be added by the FDA later as the FDA gains experience with
599 resubmitted OMORs

601 Class Two resubmitted original OMORs are resubmissions that include any other items,
602 including any items that the FDA decides would need presentation to an Advisory Committee.

603
604 The FDA and Industry do not expect any resubmitted original OMORs during the first five years
605 of a user fee agreement.

606
607 If any resubmissions of original OMORs occur, the following timelines will apply:
608

Table II.B.1.j: Timelines for Resubmitted Original OMORs		
	Class One Resubmission	Class Two Resubmission
Issuance of proposed order	FDA issues proposed order 4 months after receipt of resubmitted original OMOR	FDA issues proposed order 6 months after receipt of resubmitted original OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness¹ of comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order²	FDA issues final order 9.5 months after receipt of Class I resubmitted original OMOR	FDA issues final order 11.5 months after receipt of Class I resubmitted original OMOR
Abbreviation: OMOR = Over-the-Counter Monograph Order Request 1 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review. 2 If comments received are numerous or substantive, there will be a Comment Review Extension of the final order goal date by 5 months, for both Class I and Class II resubmitted original OMORs		

609

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610 Comment Review Extension: If comments received during the comment period are numerous
611 or substantive, there will be an extension of the final order goal date by 5 months, for both
612 Class One and Class Two resubmitted original OMORs.

613

614 Performance Goal:

615

616 Year 5: For 50% of resubmitted original OMORs received in Year 5, FDA will issue a final order
617 by the specified goal date

618

619 2. Guidance Development for Innovation

620

621 Under the proposed policy reforms for the monograph, most innovations would occur through
622 submission of an OMOR by an Industry requestor. However, it is possible that a few types of
623 changes to the monograph could be accomplished through a process that would not require an
624 OMOR for each change. One area where such changes might occur is for minor dosage form
625 changes.

626 In order to clarify which types of minor changes to solid oral dosage forms might be possible
627 without an OMOR (when the monograph does not already provide for these types of changes),
628 FDA will issue a proposed administrative order outlining key requirements, and draft guidance
629 providing details of what sponsors will need to do in order to comply with the proposed
630 administrative order. This order and guidance are referred to together as an “order/guidance
631 pair”. FDA will issue the proposed administrative order and draft guidance by April 1, 2022.

632 C. Enhancing Communication and Transparency for the Public and Regulated
633 Industry

634

635 1. Meeting Management Goals

636

637 Formal OMUFA meetings between monograph sponsors/requestors and FDA will consist of
638 Type X, Y, and Z meetings. These meetings are further described below.

639

640 Type X meetings are those meetings that are necessary for an otherwise stalled monograph
641 drug development program to proceed, or meetings that are necessary to address an important
642 safety issue. A meeting requested by an Industry requestor within 3 months after FDA has
643 taken a refusal-to-file action on an OMOR submitted by that requestor would be a Type X
644 meeting. A meeting requested by an Industry requestor within 3 months after FDA has declined
645 to issue an administrative order requested by that requestor would be a Type X meeting.

646

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647 Type Y meetings are intended for milestone discussions during the lifecycle of Industry
 648 development programs for monograph ingredients and monograph conditions of use. Examples
 649 of appropriate circumstances for Type Y meetings include:

- 650 • Overall Data Requirements Meetings: After FDA has stated its intent to make a final
 651 GRASE determination for a particular monograph ingredient or monograph condition of
 652 use, an Industry sponsor may request a meeting to discuss the overall data
 653 requirements to support that GRASE determination. Similarly, an Industry sponsor
 654 interested in initiating an OMOR for an FDA action on a monograph ingredient or
 655 monograph condition of use may request a meeting to discuss the overall data
 656 requirements to support that OMOR.
- 657 • Presubmission Meetings: When an Industry sponsor is nearing completion of its
 658 development program for an OMOR package, the sponsor may request a meeting to
 659 present a summary of the data supporting the proposed OMOR, and of the proposed
 660 format for the OMOR package, to obtain FDA feedback on the adequacy of the
 661 proposed package. For an Innovation OMOR, the proposed Tier (One or Two) may also
 662 be discussed at the presubmission meeting. The presubmission meeting should be held
 663 sufficiently in advance of the planned submission of the order request to allow for
 664 meaningful response to FDA feedback and should generally occur not less than 3
 665 months prior to the planned submission of the order request.

667 A Type Z meeting is any other type of meeting.

668
 669 a. Responses to Meeting Requests

670
 671 Procedure: FDA will notify the requestor in writing of the date, time, and place for the meeting,
 672 as well as expected FDA participants, following receipt of a formal meeting request. Table
 673 II.C.1.a below indicates the timeframes for FDA’s response to a meeting request.

Table II.C.1.a: Meeting Request Response Time Goals	
Meeting Type	Response Time (calendar days)
X	14
Y	14
Z	21

- 675
 676 • For any type of meeting, the requestor may request a written response to its questions
 677 rather than a face-to-face meeting or teleconference. FDA will review the request and
 678 make a determination regarding whether a written response is appropriate or whether

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679 a face-to-face meeting or teleconference is necessary. If FDA deems a written response
680 appropriate, when FDA responds to the meeting request, FDA will notify the requestor
681 of the date FDA intends to send the written response. This date will be consistent with
682 the timeframes specified in Table II.C.1.b below for the specific meeting type.

- 683 • For Type Z meetings, while the requestor may request a face-to-face meeting, FDA may
684 determine that a written response to the requestor's questions would be the most
685 appropriate means for providing feedback and advice to the requestor. When it is
686 determined that the meeting request can be appropriately addressed through a written
687 response, FDA will, in FDA's response to the meeting request, notify the requestor of
688 the date FDA intends to send the written response. This date will be consistent with the
689 timeframes specified in II.C.1.b below for the specific meeting type.

690

691 b. Meeting Scheduling

692

693 Procedure: FDA will schedule the meeting on the next available date at which all applicable FDA
694 personnel are available to attend, consistent with the FDA's other business; however, the
695 meeting should be scheduled consistent with the type of meeting requested. Table II.C.1.b
696 below indicates the timeframes for the scheduled meeting date following receipt of a formal
697 meeting request, or in the case of a written response, the timeframes for FDA to send the
698 written response. If the date requested by the requestor for any meeting type is greater than
699 the specified timeframe, the meeting date should be within 14 calendar days of the requested
700 date.

701

Table II.C.1.b: Meeting Scheduling or Written Response Times	
Meeting Type	Meeting Scheduling or Written Response Time
X	30 calendar days from receipt of meeting request
Y	70 calendar days from receipt of meeting request
Z	75 calendar days from receipt of meeting request

702

703 See Section II.C.1.h for meeting performance goals.

704

705 c. Meeting Background Packages

706

707 The requestor of the requested meeting will submit the background package for each meeting
708 type no later than the date specified in Table II.C.1.c below.

709

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Table II.C.1.c: Timelines for Submission of Meeting Background Packages	
Meeting Type	Receipt of Background Package
X	At the time of the meeting request
Y	50 calendar days before the date of the meeting or expected written response
Z	47 calendar days before the date of the meeting or expected written response

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d. Preliminary Responses to Requestor Questions

Procedure: FDA will send preliminary responses to the requestor’s questions contained in the background package no later than five calendar days before the meeting date for Type Y and Z meetings. FDA will generally not send preliminary responses for Type X meetings.

See Section II.C.1.h for meeting performance goals.

e. Requestor Notification to FDA Regarding Whether Meeting is Still Needed, and Anticipated Agenda

Not later than three calendar days following the requestor’s receipt of FDA’s preliminary responses for a Type Y or Z meeting, the requestor will notify FDA of whether the meeting is still needed, and if it is, the anticipated agenda of the meeting given the requestor’s review of the preliminary responses.

f. Meeting Minutes

Procedure: FDA will prepare minutes that will be available to the requestor 30 calendar days after the meeting. The minutes will clearly outline the important agreements, disagreements, issues for further discussion, and action items from the meeting, in bulleted form, and need not be in great detail. Meeting minutes are not required if FDA transmits a written response for any meeting type.

See Section II.C.1.h for meeting performance goals.

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739 g. Assumptions Regarding Number of Meetings Industry Expects to Request per Year

740

741 Industry has estimated that approximately the following numbers of meetings will be
742 requested per year:

743

744 FY 2018: 6 meetings (not under timelines or performance goals)

745 FY 2019: 9 meetings (not under timelines or performance goals)

746 FY 2020: 12 meetings (see performance goal below)

747 FY 2021: 24 meeting requests (see performance goal below)

748 FY 2022: 40 meeting requests (see performance goal below)

749

750 h. Performance Goals

751

752 Requestors may submit meeting requests beginning in FY 2018. However, performance goals
753 regarding meeting management will become effective October 1, 2019. These goals are:

- 754 • Year 3: For the first 12 meeting requests received in Year 3, FDA will meet 50% of the
755 total of meeting management goal dates (goal dates for response, scheduling,
756 preliminary responses [Type Y meetings only], and minutes). If more than 12 meeting
757 requests are submitted in Year 3, the remainder will not be under timelines.
- 758 • Year 4: For meeting requests received in Year 4, FDA will meet 60% of the total of
759 meeting management goal dates (goal dates for response, scheduling, preliminary
760 responses [Type Y meetings only], and minutes)
- 761 • Year 5: For meeting requests received in Year 5, FDA will meet 80% of the total of
762 meeting management goal dates (goal dates for response, scheduling, preliminary
763 responses [Type Y meetings only], and minutes)

764

765 Performance goals apply to the aggregate of all types of meeting management goals. However,
766 in FDA's OMUFA performance report, FDA will include information on the various subsets of
767 meeting management goals.

768

769 i. Conditions for Performance Goals for Meetings

770

771 For a meeting to qualify for OMUFA performance goals, all of the following conditions must be
772 met:

- 773 • The meeting must concern issues related to the issuance of an administrative order for
774 the monograph, issues related to a potential request for a monograph order, or issues
775 related to FDA-initiated data requests for the monograph.
- 776 • The requestor of the meeting must be subject to, or potentially subject to, OMUFA fees.
777 For example, the requestor may be a monograph establishment owner, a requestor of
778 an OMOR, or a requestor who intends to submit an OMOR. Other entities may request

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- 779 meetings to discuss monograph issues, but meetings with these other entities will not
780 qualify for OMUFA performance goals.
- 781 • A written request must be submitted to the review division.
 - 782 • The written request must provide:
 - 783 ○ A brief statement of the purpose of the meeting and the requestor's proposal for
 - 784 either a face-to-face meeting or a written response from FDA
 - 785 ○ A listing of the specific objectives/outcomes the requestor expects from the
 - 786 meeting
 - 787 ○ A proposed agenda, including estimated times needed for each agenda item
 - 788 ○ A statement of whether the requestor intends to discuss trade secret or
 - 789 confidential commercial information at the meeting
 - 790 ○ A listing of planned external attendees
 - 791 ○ A listing of requested participants or discipline representatives from the Center
 - 792 with an explanation for the request as appropriate
 - 793 ○ The date that the meeting background package will be sent to the Center. Refer
 - 794 to Table II.C.1.c for timeframes for FDA's receipt of background packages.
 - 795 • FDA must concur that the meeting will serve a useful purpose (i.e., the meeting is not
 - 796 premature or clearly unnecessary). However, requests for Type Y meetings will be
 - 797 honored except in the most unusual circumstances.
 - 798 • The requestor of the meeting and any of its affiliates must have no overdue unpaid
 - 799 OMUFA fee.

800 801 j. Meetings Guidance Development

802
803 FDA will develop guidance regarding formal meetings between FDA and sponsors or requestors
804 for OMUFA ingredients and drug products. FDA will issue draft guidance by February 1, 2019.
805 FDA will issue final guidance by July 1, 2020.

806 807 2. FDA Forecasting of Planned Monograph Activities

808
809 Procedure: Each year, FDA will publish a nonbinding listing of monograph issues FDA intends to
810 address in the coming three years. For issues for which FDA anticipates that submission of data
811 to FDA will likely be needed, FDA will include a date by which it will expect these data to be
812 submitted. FDA will publish the first list by October 1, 2018; and will publish subsequent lists no
813 less frequently than annually (by October 1 in each of the years 2019, 2020 and 2021.)

814
815 Performance goal: FDA will publish each annual forecasting list within 30 days of the goal date.

816
817
818

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819 D. Enhancing Industry's and FDA's Core Mission Efforts to Ensure and Improve
820 the Safety of OTC Monograph Drugs

821
822 Prior to the proposed monograph reforms, it has been very difficult and time-consuming to
823 effect changes to monographs, with changes often requiring many years. The significance of
824 this difficulty in changing monographs in a timely manner has been especially problematic
825 when the desired changes have been intended to change the labeling of monograph products
826 to enhance the likelihood of safe use of the product. As noted in sections on timelines for
827 Industry-initiated Innovation OMORs and Industry-requested GRASE Finalization OMORs, FDA
828 intends to reduce the time needed for action on monograph issues, going from the current
829 reality of many years for each change, to a timeframe of less than two years in most
830 circumstances, while still maintaining public comment between proposed and final orders, and
831 maintaining FDA's standards for safety and efficacy.

832
833 For certain Industry-requested safety changes to the Drug Facts labeling of monograph drug
834 products, FDA intends an even shorter timeline, as described below.

835
836 The following types of proposed changes to the Drug Facts label of monograph drug products
837 qualify for the shorter timeline:

838
839 Changes to the Drug Facts labeling of a monograph drug that are intended to add or strengthen
840 any of the following:

- 841 • a contraindication, warning, precaution, or adverse reaction
- 842 • a statement about risk associated with misuse or abuse
- 843 • an instruction about dosage and administration that is intended to increase the safe
844 use of the monograph drug product

845
846 OMORs for these types of changes will hereafter be referred to as "Specified Safety Change
847 OMORs." These industry-requested Specified Safety Change OMORs will be made through the
848 ordinary administrative order process proposed under monograph reform (and not through the
849 interim final order expedited procedure for administrative orders proposed under monograph
850 reform.)

851
852 In order to qualify for the shortened timelines, OMORs for these types of safety changes are to
853 be submitted as stand-alone packages, and are not to include requests for other types of
854 changes to a monograph. A filing determination will be made, and if an OMOR that is
855 represented by the requestor as fitting into one of the above DFL safety change categories is
856 determined to contain a request for another type of change to the monograph, the applicable
857 timeline will be consistent with that for the other type of request found in the OMOR.

858
859

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860 1. Timelines for Industry-Requested Specified Safety Change OMORs

861

Table II.D.1: Timeline for Industry-Initiated Request for Certain² Safety-Related Changes to the Drug Facts Labeling of Monograph Drug Products (“Specified Safety Change OMORs”)	
Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 6 months after receipt of OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness¹ of comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order³	11.5 months after receipt of OMOR
<p>Abbreviation: OMOR = Over-the-Counter Monograph Order Request</p> <p>¹ Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review.</p> <p>² Changes to the Drug Facts labeling of a monograph drug that are intended to add or strengthen any of the following:</p> <ul style="list-style-type: none"> • a contraindication, warning, precaution, or adverse reaction • a statement about risk associated with misuse or abuse • an instruction about dosage and administration that is intended to increase the safe use of the monograph drug product <p>³ If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 3 months.</p>	

862

863 2. Assumptions Regarding the Number of Specified Safety Change OMORs Industry Expects
864 to Submit During the First Five Years of OMUFA

865

866 Across the first five years of OMUFA, Industry estimates that it will submit a total of two
867 OMORs for the above types of safety-related changes.

868

869 3. Performance Goals

870

871 Timelines and performance goals will begin on October 1, 2020.

872

873 Requestors may submit OMORs for the above types of safety-related changes in Years 1-3, but
874 timelines and performance goals will not apply in those years. However, FDA always strives to
875 review safety data and make appropriate changes in a timely manner.

876

877 Performance Goals:

- 878 • Year 4: For 60% of OMOR submissions that request the above types of safety changes,
879 and that are received in Year 4, FDA will issue a final order by the specified goal date
- 880 • Year 5: For 80% of OMOR submissions that request the above types of safety changes,
881 and that are received in Year 5, FDA will issue a final order by the specified goal date

882

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883 4. Timelines for FDA-Requested Safety Changes

884

885 The above timelines and performance goals apply to Industry-requested specified safety
886 changes. Other Industry-requested changes to the monograph, even if possibly related to
887 safety, will be subject to the same timelines for other OMORs as outlined in Section II.B.1.d.

888

889 Under the proposed monograph reforms, two types of FDA-requested safety changes to the
890 monograph are included. One type will include a proposed order, followed by a comment
891 period, followed by a final order. Another type, to be used for certain serious safety concerns
892 defined in the policy reform statutory language, will include an interim final order (that will go
893 into effect immediately), followed by a comment period, followed by a final order. Once FDA
894 has issued an FDA-initiated proposed safety order, or an FDA-initiated interim final order for a
895 safety issue, FDA intends to follow the same timelines outlined in Table II.D.1 above regarding
896 the length of the comment period and lengths of time from the end of the comment period to
897 issuance of a final order.

898

899 5. Major Amendments

900

901 Major Amendments will be possible; see Section II.B.1.h for further information.

902

903 6. Comment Review Extension

904

905 Comment Review Extension: If comments received during the comment period are
906 numerous or substantive, there will be an extension of the final order goal date by 3
907 months. This extension will be additive to those generated by any major amendment(s).

908

909 7. Resubmitted Original OMORs

910

911 See Section II.B.1.j.

912

913 E. Enhancing Efficiency in Continuing FDA's Core Mission Work of Completion of 914 Final GRASE Determinations of Monograph Ingredients

915

916 FDA will continue work on finalization of GRASE determinations for ingredients that were
917 Category III in a TFM prior to monograph reform, and for ingredients that were proposed as
918 Category I in an ANPR prior to monograph reform. FDA will request that Industry submit data
919 packages to support these GRASE finalizations.

920

921 When an FDA-requested complete package for a final GRASE determination (referred to as a
922 GRASE Finalization Package) is submitted, FDA intends to follow the same timelines as outlined
923 for Industry-submitted OMORs for GRASE finalizations (see below).

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924
 925 Due to the resource requirements for the many implementation activities for other aspects of
 926 monograph reform, FDA does not expect to begin to request packages until OMFUFA Year 4 or
 927 later, and even in Year 4 and the ensuing few years, will likely only have sufficient resources to
 928 review one or two packages per FY while still meeting other OMFUFA commitments. Once FDA
 929 begins to request these packages, FDA plans to request packages for up to 6 ingredients per
 930 year.

F. Enabling Efficient Completion of Final GRASE Determinations Requested by Industry

931
 932
 933
 934 As discussed above, some GRASE finalization packages will be requested by FDA. Industry can
 935 also initiate a GRASE finalization process by submitting a GRASE Finalization OMOR. All OMOR
 936 packages are expected to be complete at the time of submission. The content and format of a
 937 complete OMOR package are to be discussed at a presubmission meeting as discussed in
 938 Section II.C.1.

1. Timelines

Table II.F.1: Timeline for Review of Industry-Initiated Over-the-Counter Monograph Order Requests for Final GRASE Determinations (GRASE Finalization OMORs)

Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness¹ of comments.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order²	17.5 months after receipt of OMOR

Abbreviations: GRASE = General Recognition of Safety and Effectiveness; OMOR = Over-the-Counter Monograph Order Request

¹ Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review.

² If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 6 months.

2. Assumptions Regarding the Number of GRASE Finalization OMORs Industry Expects to Submit in the First Five Years of OMFUFA

943
 944
 945
 946
 947 Based on discussions between Industry and FDA, an assumption was made that no Industry-
 948 initiated requests for GRASE finalizations for existing nonfinal ingredients are likely during the
 949 first cycle of OMFUFA, as Industry is expected to be more likely to submit Innovation OMORs and
 950 Specified Safety Change OMORs in the first cycle.

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3. Performance Goal

Timelines and performance goals for Industry-requested GRASE Finalization OMORs will begin in Year 5.

Although there will not be timelines and performance goals associated with GRASE Finalization OMORs submitted in years 1-4, requestors may still submit them.

Performance Goal:

FY 2022: For 50% of GRASE Finalization OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date

4. Major Amendments

Major Amendments will be possible; see Section II.B.1.h for further information.

5. In-Review Meeting

An in-review meeting will be scheduled for Industry-submitted GRASE Finalization OMORs. See Section II.B.1.i.

6. Comment Review Extension

If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 6 months. This extension will be additive to those generated by any major amendment(s).

7. Resubmitted Original OMORs

See Section II.B.1.j.

G. Implementing a New Dispute Resolution System Agreed Upon as Part of Monograph Policy Reform

Under the proposed monograph policy reforms, two (sequential) dispute resolution processes are specified. The first is the current CDER formal dispute resolution request path, referred to here as the CDER FDRR path. If a requestor proceeds through the entire CDER FDRR path, but still wishes to dispute CDER's action, the requestor may request to proceed to a second path, referred to here as the administrative hearing path.

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992 The first path is described in the draft guidance for Industry and review staff entitled *Formal*
993 *Dispute Resolution: Appeals above the Division Level*, hereafter referred to as the FDRR
994 guidance. This guidance will need some modification of its language to encompass actions
995 covered under OMUFA. If dispute resolution is requested prior to modification of the draft
996 guidance, FDA and Industry intend to follow applicable general procedures in the above existing
997 FDRR draft guidance.

998
999 Procedure (for FDRR draft guidance development): FDA will revise the draft guidance for
1000 Industry and review staff *Formal Dispute Resolution: Appeals above the Division Level*, to state
1001 the circumstances and procedures under which requestors of OMUFA may use the CDER FDRR
1002 process. The draft guidance will be revised by February 3, 2020.

1003
1004 Performance goal (for timelines described in the FDRR draft guidance):

1005
1006 FY 2021: For dispute resolution requests received in Year 4, FDA will meet 50% of the timeline
1007 dates described in the FDRR draft guidance

1008
1009 FY 2022: For dispute resolution requests received in Year 5, FDA will meet 75% of the timeline
1010 dates described in the FDRR draft guidance

1011
1012 After a requestor has proceeded through the entire CDER FDRR path, the sponsor may request
1013 to proceed to an administrative hearing path. The above performance goals will not apply to
1014 the administrative hearing path.

1015
1016 H. Carrying Out Other Aspects of Monograph Reforms

1017
1018 1. Consolidated Proceedings Guidance

1019
1020 For monograph drugs products, it is common for there to be multiple manufacturers or
1021 sponsors of a given drug product with the same active ingredient and other monograph
1022 conditions of use.

1023
1024 For Industry-initiated OMORs, it is highly desirable that all Industry sponsors that are relevant
1025 for a given OMOR consolidate their data into a single well-organized and complete submission
1026 package.

1027
1028 For Industry-initiated appeals of FDA decisions regarding the monograph, FDA intends to
1029 conduct a single consolidated appeals process for a given appealed FDA decision, with all
1030 relevant sponsors represented as a group.

1031

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1032 It will be the responsibility of Industry to organize itself for these consolidated processes.
1033 However, FDA will issue guidance on its views regarding best practices for consolidated
1034 proceedings for appeals. FDA will issue draft guidance by July 1, 2019, and will issue final
1035 guidance by February 1, 2021.

1036
1037 2. Administrative Activities for Category I Ingredients and Other Monograph Conditions of
1038 Use from Tentative Final Monographs

1039
1040 Under the proposed monograph reforms, TFM Category I ingredients will be treated as GRASE
1041 under the monograph conditions of use specified in the TFM as it was immediately prior to
1042 enactment of monograph reform. There will be administrative activities associated with these
1043 finalizations and the associated public postings. FDA will complete these administrative
1044 activities by October 1, 2018.

1045
1046 3. Conditions that Apply to Over-the-Counter Monograph Order Requests Filed Over
1047 Protest

1048

1049 Under proposed monograph reforms, FDA may refuse to file certain OMORs.

1050

1051 FDA will make a filing determination within 60 calendar days after receipt of an OMOR. FDA will
1052 issue a letter (a "Day 74 Letter") to requestors within 74 calendar days after receipt of an
1053 OMOR. The Day 74 Letter will communicate FDA's filing decision and any filing issues that were
1054 identified.

1055

1056 OMOR requestors may choose to file an OMOR over protest after a refusal-to-file decision by
1057 FDA. The following conditions will apply to OMORs filed over protest:

- 1058
- 1059 • OMORs filed over protest will be subject to the same timelines and performance goals
outlined in Sections II.J.1 and II.J.2.
 - 1060 • OMORs filed over protest will not be eligible for in-review meetings with FDA
 - 1061 • FDA generally will not review amendments to OMORs filed over protest
 - 1062 • FDA generally will not issue information requests to requestors of OMORs filed over
1063 protest
 - 1064 • The timelines for resubmitted original OMOR reviews will not apply to resubmission of
1065 an OMOR that was filed over protest. Any such resubmission will be reviewed as
1066 available resources permit.

1067

1068 I. Routine Inspections

1069

1070 For routine FDA inspections of monograph drug manufacturing facilities, FDA intends to
1071 continue to follow a risk-based model for prioritization of inspections.

1072

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1073 J. Creating a System to Measure the Success of Goals Laid Out in the User Fee
1074 Agreement

1075
1076 1. Summary of Performance Goals for OMUFA

1077
1078 As noted earlier, when there are very few instances of a given activity, adherence to
1079 performance goals should be interpreted accordingly. For example, if there are so few
1080 occurrences of an activity that missing only one or two goal dates would make it appear that
1081 the performance goal was not met, qualitative description of performance may provide more
1082 useful data to be used in improving future performance.

1083
1084 As discussed in Section II.A.2, the growth of effective review capacity will be limited in the first
1085 three years of OMUFA due to the necessary training of newly onboarded hires, and during
1086 those first three years, much of the effective review capacity will be consumed by current
1087 mandates such as the Sunscreen Innovation Act and an antiseptic consent decree, and by
1088 ongoing safety activities. There are also numerous OMUFA implementation and infrastructure
1089 establishment activities to be accomplished in those years, resulting in a likely “net-negative”
1090 effective review capacity in Years 1-3. Beginning in Year 4 (and to a very limited extent in Year
1091 3), FDA expects to have built sufficient effective review capacity to begin to implement
1092 timelines and limited performance goals.

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1113 The following table summarizes performance goals for OMUFA activities for the first 5 years of
 1114 OMUFA:
 1115

Table II.J.1: Summary of Performance Goals for OMUFA	
Activity	Performance Goal
Industry-Submitted Innovation OMORs	Year 4: For 50% of OMOR submissions received in Year 4, FDA will issue a final order by the specified goal date Year 5: For 75% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Industry-Submitted Specified Safety Change OMORs	Year 4: For 60% of OMOR submissions received in Year 4, FDA will issue a final order by the specified goal date Year 5: For 80% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Industry-Submitted GRASE Finalization OMORs	Year 5: For 50% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Resubmitted Original OMORs	Year 5: For 50% of resubmitted original OMORs received in Year 5, FDA will issue a final order by the specified goal date
Meetings between FDA and regulated monograph Industry	Year 3: For the first 12 meeting requests received in Year 3, FDA will meet 50% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes). If more than 12 meeting requests are submitted in Year 3, the remainder will not be under timelines. Year 4: For meeting requests received in Year 4, FDA will meet 60% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes) Year 5: For meeting requests received in Year 4, FDA will meet 80% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes)
Issuance of nonbinding annual forecasting list of planned monograph actions over ensuing 3 years	FDA will publish the forecasting list within 30 days of each goal date (goal dates are Oct 1 of 2018, 2019, 2020, and 2021).
Dispute resolution	Year 4: For dispute resolution requests received in Year 4, FDA will meet 50% of the timeline dates described in the FDRR draft guidance Year 5: For dispute resolution requests received in Year 5, FDA will meet 75% of the timeline dates described in the FDRR draft guidance
Abbreviations: DFL = Drug Facts label; FY = fiscal year; FDRR = Formal Dispute Resolution Request; OMOR = Over-the-Counter Monograph Order Request	

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1116 2. Summary of Timelines for Industry-Initiated Over-the-Counter Monograph Order Requests

1117

1118 The following table summarizes the timelines for Industry-initiated OMORs.

1119

Table II.J.2: Summary of Timelines for Industry-Initiated Requests for Monograph Actions							
	Tier One Innovation OMOR: Eligible¹ New Ingredient	Tier One Innovation OMOR: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other² Monograph Change	Tier Two Innovation OMOR	GRASE Finalization OMOR	Specified Safety Change OMOR	Class One Resubmitted⁵ Original OMOR	Class Two Resubmitted⁵ Original OMOR
Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	n/a	n/a
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 10 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 6 months after receipt of OMOR	FDA issues ⁵ proposed order 4 months after receipt of resubmitted OMOR	FDA issues ⁵ proposed order 6 months after receipt of resubmitted OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days

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Table II.J.2: Summary of Timelines for Industry-Initiated Requests for Monograph Actions							
	Tier One Innovation OMOR: Eligible¹ New Ingredient	Tier One Innovation OMOR: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other² Monograph Change	Tier Two Innovation OMOR	GRASE Finalization OMOR	Specified Safety Change OMOR	Class One Resubmitted⁵ Original OMOR	Class Two Resubmitted⁵ Original OMOR
Assessment of volume and substantiveness³ of comments.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order⁴	17.5 months after receipt of OMOR	17.5 months after receipt of OMOR	15.5 months after receipt of OMOR	17.5 months after receipt of OMOR	11.5 months after receipt of OMOR	9.5 months after receipt of resubmitted OMOR	11.5 months after receipt of resubmitted OMOR
<p>Abbreviations: GRASE = generally recognized as safe and effective; OMOR = over-the-counter monograph order request</p> <p>1 See Section II.B.1.d regarding eligibility determination</p> <p>2 This includes all proposed changes to the monograph, except for safety changes described in Section II.D, the addition of new ingredients, Tier Two Innovation OMORs, and specific changes for which FDA has issued a final guidance stating that an OMOR is not required (see Section II.B.2).</p> <p>3 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or full review.</p> <p>4 If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date. See Sections II.B.1.e, II.B.1.j, II.D.6, and II.F.6.</p> <p>5 Assumes resubmitter addressed all deficiencies identified in the previous final order</p>							

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3. Summary of Dates of Specified Activities under OMuFA

Table II.J.3: Summary of Dates of Specified¹ Activities under OMuFA															
Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Assumed effective date	x														
Hiring annual goal assessment		x				x				x			x		
Monograph forecast annual posting		x				x				x			x		
TFM Cat I finalization activities complete		x													
Meetings draft guidance issued			x												
Meetings final guidance issued								x							
Public-facing IT dashboard contract awarded		x													
Public-facing IT dashboard functional						x									
IT platform for electronic submission receipt, archiving and reporting: RFP			x												
IT platform: initial contracts awarded				x											
IT platform: business requirements established								x							
IT platform fully functional															x
Content and format draft guidance issued				x											
Content and format final guidance issued										x					
Consolidated proceedings draft guidance issued					x										
Consolidated proceedings final guidance issued											x				

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Table II.J.3: Summary of Dates of Specified ¹ Activities under OMUFA															
Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Meeting management TPGs begin						x									
Meeting management TPGs annual goal assessment										x			x		
Electronic submission draft guidance issued						x									
Electronic submission final guidance issued												x			
CDER-level dispute resolution updated draft guidance issued							x								
Pre-OMUFA paper document cataloging contract award							x								
Pre-OMUFA paper document cataloging complete														x	
Innovation OMOR TPGs begin											x				
Industry-initiated Specified Safety Change OMORs TPGs begin											x				
Industry-initiated GRASE Finalization OMOR TPGs begin													x		
CDER-level dispute resolution TPGs begin											x				
Solid oral dosage forms proposed administrative order and draft guidance issued															x

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Table II.J.3: Summary of Dates of Specified¹ Activities under OMUFA															
Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Abbreviations: ANPR = Advance Notice of Proposed Rulemaking; CAT = category; CDER = Center for Drug Evaluation and Research; COU = monograph conditions of use; GRASE = generally recognized as safe and effective; IT = information technology; OMOR = Over-the-Counter Monograph Order Request; OMUFA = Over-the-Counter Monograph User Fee Act; TFM = Tentative Final Monograph; TPGs = timelines and performance goals 1: These are not all the activities that the FDA monograph review staff will be engaged in, but only those for which goal dates are specified under OMUFA. FDA will continue its many baseline monograph activities, such as: addressing ongoing and emerging safety issues; carrying out mandated activities under the Sunscreen Innovation Act and an antiseptic consent decree; training; and numerous other activities described elsewhere in this goals document															

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1127 4. Annual Performance Reporting

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1129 FDA will include in the public annual performance report to Congress an assessment of the
1130 activities listed in Table II.J.3 "Summary of Dates of Specified Activities under OMUFA."

1131

1132 III. Definitions and Explanations of Terms

1133

1134 (If needed, will be added later to be consistent with statutory language)