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FDA Product-Specific Guidance Revisions: ANDA Impact Matrix

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Executive Summary

On 21 August 2026 the U.S. Food and Drug Administration (FDA) released a batch of **55 draft product-specific guidances (PSGs)** for generic drug development, of which **24 were new and 31 were revised**, and **18 were for complex products** (www.fda.gov). The Federal Register notice (91 FR 54722) set a comment deadline of **23 October 2026** (www.federalregister.gov), so three days remain as of 20 October 2026. Every PSG in the batch is a draft, and FDA states that it considers all docket comments before finalizing (www.fda.gov).

FDA classifies planned PSG revisions as **critical, in vivo major, in vitro major, minor or editorial** (www.fda.gov). Only the critical category is described by FDA as having a potential impact on all abbreviated new drug applications (ANDAs), including approved ones (www.fda.gov). For major revisions, FDA offers a PSG teleconference to applicants that have already commenced an in vivo bioequivalence (BE) study, defined as a protocol signed by the sponsor and/or the contract research organization (CRO) (www.fda.gov). The upcoming list is a plan, not a promise: FDA states that timing may be subject to change (www.fda.gov), and rows on the page already carry notes such as a planned date moving to a later date (www.fda.gov).

The practical decision is therefore two-dimensional: which revision category applies, and which lifecycle state each affected program is in (protocol unsigned, signed or ongoing, completed, pending ANDA, approved ANDA). This report maps the two onto a reference matrix and a minimum change register, with explicit flags for where a BE or regulatory specialist and FDA engagement are needed. The matrix is an internal control design, not an FDA rule. FDA guidance does not establish legally enforceable responsibilities (www.ecfr.gov), and the sources reviewed document no automatic obligation for most category and stage combinations.

A worked example shows why identity matching and source versioning matter. FDA's announcement says the new PSG for TWYNEO (NDA 214902) recommends in vitro studies and characterization tests as an alternative option (www.fda.gov). The PSG PDF retrieved on 20 October 2026 lists a comparative clinical endpoint study under "Recommended Studies" (www.accessdata.fda.gov), and its text contains no in vitro option. That unresolved mismatch is recorded, not resolved, and no universal eligibility is inferred.

Workload can be sized with a user-supplied formula (affected protocols multiplied by estimated review hours), illustrated below with hypothetical inputs. No benchmark, savings figure or client outcome is claimed. FDA-TRACK data list only two PSG teleconference requests submitted between October 2025 and August 2026 (www.fda.gov). The data do not show how many sponsors were eligible, so no uptake rate can be calculated.

Introduction and Background

Product-specific guidances are FDA's recommendations on how to develop a generic product therapeutically equivalent to a specific reference listed drug (RLD). FDA describes them as its current thinking and expectations (www.fda.gov), and says it routinely posts and revises them (www.fda.gov). The statute underneath is the Federal Food, Drug, and Cosmetic Act: an ANDA must contain information showing that the generic is bioequivalent to the listed drug (www.govinfo.gov), and the Secretary may refuse approval when that information is insufficient (www.govinfo.gov). The implementing regulation repeats the requirement (www.ecfr.gov). None of those texts mentions a PSG. The PSG is the agency's product-level statement of how to meet them.

A review of a competing explainer shows the gap this report addresses: the DDReg article describes searchable regional databases for BE guidance (resource.ddregpharma.com) and notes that generic regulations face constant updates and revisions (resource.ddregpharma.com), but it names only the US and EMA repositories (resource.ddregpharma.com) and describes no workflow for what to do when a recommendation changes.

Scale explains why a workflow matters. FDA reported 2,288 PSGs published as of 30 September 2025 (www.fda.gov), and in fiscal year (FY) 2025 it issued 925, a count dominated by a single alignment exercise discussed in the data section (www.fda.gov). FDA also approved 689 ANDAs in FY 2025 (www.fda.gov). A sponsor with dozens of products, several CROs and multiple filing stages cannot rely on memory to notice that one reference product's recommendation changed.

This report is written from the perspective of an adjacent advisory firm, not a PSG source and not a software vendor. It does not offer clinical, regulatory or legal advice, and every product-level conclusion should be validated by a BE and regulatory specialist and, where the sources below indicate, by FDA. Optional related reading on dissolution and similarity testing is available in [an existing article on dissolution testing and f2 similarity](#); it is not used as evidence here, and this report stays on the decision when recommendations change.

Key Changes: The August 2026 Batch and the Next Planned Release

The 21 August 2026 batch, counted correctly

FDA's announcement states that the agency published a new batch of draft PSGs (www.fda.gov), with more than 30 for products with no approved ANDAs, including 15 for complex products (www.fda.gov). The Federal Register notice was filed on 21 August and published on 24 August 2026 (public-inspection.federalregister.gov). It lists new drafts in one table (public-inspection.federalregister.gov) and revised drafts in a second (public-inspection.federalregister.gov) by active ingredient, so it cannot by itself identify a strength, dosage form or study design. Independent trade coverage reports the same 24 and 31 split (oncodaily.com). One of those articles is labeled AI-assisted and is used here only to show how the batch was reported, not as evidence of FDA's position (www.pharmanow.live).

Counting discipline matters for any register. The 55 figure counts guidance PDFs. The upcoming list counts rows, one per application, form and category combination. The two should never be added together or reconciled by subtraction, and the "18 complex" and "more than 30 with no approved ANDA" figures are overlapping subsets of the 55, not additional items (www.fda.gov).

Source hierarchy for a revision

Five source types carry different authority, and a register should record which one supports each statement.

- **Individual PSG PDF.** The only source of the actual recommendation text, its document history and its draft or final marking. The TWYNEO PDF states "Recommended Aug 2026" in its document history (www.accessdata.fda.gov).

- **Published PSG database.** FDA's discovery tool, which the announcement links as the home of PSGs (www.fda.gov). In this research the database page could not be retrieved by automated fetch, so no database-only fact is asserted.
- **Upcoming PSG list.** FDA's twelve-month look-ahead (www.fda.gov), with planned revision categories and brief descriptions (www.fda.gov). Each update removes published PSGs and adds new plans (www.fda.gov), so a plan disappears from the page once issued. Snapshots must be taken before each update.
- **General guidances and regulations.** FDA's pharmacokinetic-endpoint BE guidance tells applicants to consult routinely published PSGs (www.fda.gov) and says a PSG's recommendations generally supersede the guidance's own topic-specific text (www.fda.gov).
- **FDA correspondence.** Meeting minutes, controlled correspondence and teleconference feedback are the only sources that speak to one sponsor's program. A 2025 paper by FDA authors says PSG prioritization weighs items such as PSG docket comments, controlled correspondences and citizen petitions (pmc.ncbi.nlm.nih.gov).

Table 1 below separates published from planned status, because a planned revision is not a published recommendation and a draft is not a final one.

Status	What FDA publishes	What a register should record	What it does not establish
Planned revision	A row on the upcoming list with a planned month, category and brief description (www.fda.gov)	Row text verbatim, list "Updated" date, planned date	A recommendation, a deadline or a study change; FDA states timing may change (www.fda.gov)
Published draft PSG	A PDF in the batch, announced in the Federal Register (public-inspection.federalregister.gov)	URL, issue date, PDF hash, revision text, draft marking	A final position; FDA considers docket comments before finalizing (www.fda.gov)
Final PSG	A PSG finalized after comment review (www.fda.gov)	Same fields plus link to the superseded draft	A binding rule; guidance does not legally bind the public or FDA (www.ecfr.gov)
Withdrawn PSG	Listed in a withdrawn-PSG document FDA links from its PSG page (www.fda.gov)	Withdrawal date and replacement, if any	A recommendation to follow

Table 1 shows that status is a required classification field of a register entry, not a unique key, because planned, draft, final and withdrawn statuses recur across many documents. Each guidance-version record should carry its own unique identifier, with planned rows, retrieved document versions and product matches linked through explicit identifiers. The interpretive consequence is that a change-control system should hold a planned row and its later published PDF as two linked records, with the first closed rather than overwritten when the second appears.

Definitions of the revision categories

FDA's definitions are short, and the register should store them verbatim rather than paraphrased.

- **Critical revision:** FDA describes it as a revision that includes additional BE studies or evidence "necessary to establish BE" reflecting a change in the safety or effectiveness of the product (www.fda.gov). It has a potential impact on all ANDAs including approved applications (www.fda.gov), and holders of approved applications are expected to address the change (www.fda.gov).
- **In vivo major revision:** additional in vivo BE studies or evidence recommended to support approval (www.fda.gov).
- **In vitro major revision:** additional in vitro BE studies or evidence recommended to support approval (www.fda.gov).
- **Minor revision:** any revision not considered critical or major (www.fda.gov), explicitly including adding an in vivo or in vitro BE option (www.fda.gov) and adding information on newly approved RLD strengths (www.fda.gov).
- **Editorial revision:** non-substantive changes such as updating references, correcting grammar and streamlining format (www.fda.gov).

Row text on the live list illustrates the vocabulary. One planned row reads "Add an in vitro BE option" (www.fda.gov), another "Clarify in vitro study design" (www.fda.gov), and another "Change in study design for in vivo BE study (ies)" (www.fda.gov). One row also carries the spelling "Editoiral Revision: Update the language" (www.fda.gov). A register should preserve such text exactly, typographical errors included, because matching on normalized text would silently change the source.

Engagement routes FDA documents

Under the Generic Drug User Fee Amendments of 2022 (GDUFA III), an applicant or prospective applicant whose in vivo BE study protocol was signed before the PSG publication date may request a PSG teleconference on the potential impact of a new or revised PSG that introduces or revises an in vivo BE recommendation (www.fda.gov). The commitment letter requires the request to include the signature page of the in vivo protocol (www.fda.gov) and says FDA will hold the teleconference within 30 days of receipt (www.fda.gov). Pre-submission or post-submission PSG meetings may follow (www.fda.gov), scheduled within 120 days (no ANDA yet submitted) (www.fda.gov) or within 90 days (ANDA submitted) (www.fda.gov). FDA's meetings guidance adds that a post-submission teleconference is available when the ANDA has been submitted and the applicant has commenced or completed an in vivo study (www.fda.gov), and that during an assessment cycle FDA recommends not requesting a post-submission PSG meeting until after a discipline review letter or complete response letter (www.fda.gov).

Two boundaries follow from the wording. First, the teleconference is framed around in vivo studies. For an in vitro-only program, the routine pre-submission teleconference does not apply. FDA's guidance does describe two discretionary post-submission exceptions for ANDA applicants: a new PSG that recommends an in vivo BE study where the applicant did not conduct one, and a revised PSG that adds an in vivo recommendation where the previous PSG had none and the applicant commenced or completed the in vitro study; controlled correspondence is also available after a post-submission teleconference. Before submission, and subject to its own eligibility criteria, the pre-ANDA product development meeting is the documented forum for scientific exchange on study design (www.fda.gov). Second, when a revised PSG recommends only in vitro BE and the

applicant already holds an in vivo study, FDA's guidance says it generally would consider the in vivo study an acceptable approach and advises against requesting a teleconference, while recommending the ANDA justify the deviation (www.fda.gov). That is a documented scenario, not a general rule for all revisions.

Implementation Considerations and Process Changes

Decision matrix: revision category by lifecycle state

Table 2 cross-tabulates the five FDA categories with the five lifecycle states. Cells marked with a specialist flag need review by a BE or regulatory professional before any action, and cells citing FDA text are documented FDA positions. Unflagged text describes proposed internal register behavior only.

Category	Protocol not signed	Protocol signed or study ongoing	Study completed	ANDA pending	ANDA approved
Critical	Redesign review before signature; specialist flag .	PSG teleconference eligible only if the signed in vivo protocol predates the PSG publication date and the revision concerns an in vivo BE recommendation (www.fda.gov); specialist flag , FDA engagement .	Evidence package gap check; specialist flag , FDA engagement .	Possible amendment; adding a BE study is a major amendment example (www.fda.gov); FDA engagement .	FDA expects holders to address the change (www.fda.gov); specialist flag , FDA engagement .
In vivo major	Redesign review; specialist flag .	PSG teleconference eligible only if the signed protocol predates the PSG publication date and the revision concerns an in vivo BE recommendation; FDA engagement .	Compare completed design with revision text; specialist flag .	Post-submission route may apply (www.fda.gov); FDA engagement .	No documented FDA requirement in the sources reviewed; record and assess.
In vitro major	Redesign review; specialist flag .	Teleconference is framed around in vivo studies (www.fda.gov); if only in vitro work is ongoing, a product development meeting may apply if its pre-submission eligibility criteria are met (a discretionary post-submission teleconference is limited to the cases FDA describes for ANDA applicants) (www.fda.gov).	Gap check on in vitro evidence; specialist flag .	Possible amendment (www.ecfr.gov); FDA engagement .	No documented FDA requirement in the sources reviewed; record and assess.
Minor	Read revision text; adopt if beneficial.	Read revision text; confirm no design impact; escalate if unclear.	Usually informational; confirm no change to the recommended study.	Record; escalate only if the revision changes an approach already relied on.	Record only.
Editorial	Update reference copy.	Update reference copy.	Update reference copy.	Update reference copy.	Update reference copy.

Table 2 shows that escalation concentrates in the top three rows and the middle three columns. The pattern is deliberate: the stage at which FDA has documented a route (signed in vivo protocol, pending ANDA, approved ANDA under a critical revision) is where the matrix points to FDA engagement, and elsewhere it points to internal assessment. A "minor" label should not suppress review when the revision text changes the approach a program already uses; FDA's own definition of minor includes adding an option and clarifying study design (www.fda.gov), either of which can matter to a signed protocol.

Accountable owners and escalation sources can be assigned as follows.

- **Protocol not signed:** the BE study lead owns the assessment; the escalation source is the specialist reviewer and, for complex products, a pre-ANDA meeting request.
- **Signed or ongoing:** the sponsor's regulatory lead and the CRO project lead share ownership; the escalation source is the PSG teleconference request with the signature page (www.fda.gov).
- **Completed study:** the clinical or bioanalytical program owner checks the evidence package; reserve sample retention duties continue under the regulations (www.ecfr.gov) for at least five years after the application or supplemental application is approved or, if it is not approved, at least five years after completion of the bioavailability study in which the sample was used; record the applicable trigger for each study (www.ecfr.gov).
- **Pending ANDA:** the ANDA project manager owns the register entry; amendments follow the regulation (www.ecfr.gov), and submitting significant data before the end of the initial review cycle is treated as an agreement to extend that cycle (www.ecfr.gov).
- **Approved ANDA:** the post-approval regulatory lead owns the entry; supplements follow the approved-application provisions, and FDA may notify the holder to submit new in vivo BE evidence by supplement (www.ecfr.gov).

The refuse-to-accept guidance matters for the pending case. FDA states it will refuse to accept an ANDA that contains in vivo studies not recommended in the BE guidance without adequate justification (www.fda.gov), and that justification should address an approach that deviates from posted guidance (www.fda.gov). A revised PSG changes the baseline against which a deviation is judged, which is why the register records the PSG version relied on at each submission.

Minimum change register schema and identity matching

A register entry needs to answer three questions: what changed, whose program does it touch, and who decided what. *Table 3* lists the minimum fields. The first group identifies the guidance, the second identifies the product join, and the third records the human decision.

Group	Field	Content and rule
Guidance record	Source type	Planned row, draft PDF, final PDF or withdrawn; one record per PDF, never per product
	Draft or final	Copy from the PDF header; do not infer
	Issue date, planned date	Issue date from the PDF or Federal Register notice; planned date from the list with its "Updated" date (www.fda.gov)

Group	Field	Content and rule
	Revision category and text	Verbatim, including typographical errors (www.fda.gov)
	URL and PDF hash	Store the SHA-256 of the retrieved file; FDA notes it updates guidances periodically, so the hash identifies the version read
Product join	Application number	RLD or reference standard number as printed; the TWYNEO PSG prints "Reference Listed Drug: NDA 214902" (www.accessdata.fda.gov)
	Ingredient, route, form, strength	Strength as printed, e.g. "Strengths: 3%; 0.1%" (www.accessdata.fda.gov)
	Join status	Exact, partial or unmatched; unmatched joins go to a specialist queue
Impact record	Assessed systems and studies	Protocols, study reports, ANDA sections and CRO contracts reviewed
	Lifecycle state	One of the five states in Table 2
	Decision and approver	Named human decision, date and rationale; no automatic closure

Table 3 matters mostly for what it prohibits. Matching on ingredient name alone fails on the live list: the same ingredient pair, adapalene with benzoyl peroxide in a topical gel, appears for different RLD numbers across the new and revised tables, and one of those rows is a minor revision to add information on newly approved RLD strengths (www.fda.gov). Similarly, two exenatide rows share a characterization revision text (www.fda.gov) but carry different application numbers. A join must therefore use the application number plus route, form and strength, and treat the batch announcement's 55 PDFs, the list's rows and the sponsor's product records as three separate counts.

A practical note on completeness: the rendered upcoming page retrieved for this report displayed 10 rows at a time, from 58 new-PSG entries (www.fda.gov) and 32 revised-PSG entries (www.fda.gov). Only the displayed rows could be read, so the list should be ingested through the page's full table or export, not from a partial view.

Worked example: TWYNEO, NDA 214902

The example is a source-verification exercise, not guidance on how to run a study. FDA's announcement describes the new PSG for benzoyl peroxide and tretinoin topical cream (TWYNEO, NDA 214902) as recommending in vitro studies and other characterization tests as an alternative option to a comparative clinical endpoint study (www.fda.gov). Identity checks line up: the NDA approval package covers Twyneo cream (www.accessdata.fda.gov), DailyMed lists 1 mg (0.1%) tretinoin and 30 mg (3%) benzoyl peroxide per gram (dailymed.nlm.nih.gov), and the PSG prints strengths of 3% and 0.1% (www.accessdata.fda.gov) against NDA 214902 (www.accessdata.fda.gov).

The PSG PDF retrieved on 20 October 2026 (SHA-256 194000b5d07569dc814b527be299e51cefd04f52863e5e1fce31ac8ab881a19f) lists "Recommended Studies: Comparative clinical endpoint bioequivalence study" (www.accessdata.fda.gov), with a randomized, double

blind, parallel, placebo-controlled, in vivo design (www.accessdata.fda.gov) and twelve weeks of once-daily treatment (www.accessdata.fda.gov). Text extraction of that file found no in vitro option. The only route to a different approach in the text is a sentence encouraging a pre-ANDA meeting for applicants who propose an alternative approach (www.accessdata.fda.gov), and a stability caution for formulations that differ from the RLD design (www.accessdata.fda.gov). A sibling PSG for a different benzoyl peroxide cream (NDA 214510) also lists a clinical endpoint study (www.accessdata.fda.gov), which shows why ingredient-name matching would pull unrelated products.

The register should therefore hold two linked statements with their sources: the announcement's description and the PDF's recommended-study line. The mismatch is unresolved here because the PSG database entry was not retrievable. Three consequences follow. First, no sponsor should treat the in vitro option as available to its formulation without reading the final PDF and confirming with a specialist. Second, the PDF says a different approach may be proposed, and also that guidance is nonbinding (www.accessdata.fda.gov) and uses "should" to mean recommended, not required (www.accessdata.fda.gov), but the same text carves out specific regulatory or statutory requirements (www.accessdata.fda.gov). Third, if a later revision were to add an in vitro option, FDA's own definition would class it as minor, which is a reason to read minor revisions rather than skim them. No prior version of this PSG exists in the sources reviewed, so no prior-versus-current comparison is made; absent versions are recorded as unknown.

Teleconference and meeting readiness

Readiness is mostly about evidence that exists before the request. Items to hold ready:

- **Protocol signature page and date.** FDA's trigger is an in vivo protocol signed before the PSG publication date, for a PSG that introduces or revises an in vivo BE recommendation, and the commitment letter requires the signature page with the request. The register should store the signature date of each protocol version.
- **Previous recommendations.** Prior PSG text, earlier controlled correspondence and earlier meeting feedback relied on by the program, each tagged with source version.
- **The revision text.** The exact new wording and its category, copied from the PDF and the list row.
- **Specific questions.** FDA's meetings guidance frames these meetings as a place to discuss the scientific rationale for an approach other than the one recommended (www.fda.gov), so questions should name the departure and the justification.
- **Timing.** For a request that is granted under the applicable criteria, FDA commits to hold the teleconference within 30 days (www.fda.gov). A draft's comment window is a separate lever: docket comments can be submitted at any time (public-inspection.federalregister.gov) on docket FDA-2007-D-0369 (www.regulations.gov).

Monitoring, exception handling and approval workflow

A workable monitoring loop has six steps.

1. **Snapshot** the upcoming list each time it changes, since each update removes issued PSGs (www.fda.gov). FDA states it issues new and revised PSGs quarterly and as needed (www.fda.gov), and the commitment letter says it updates the website approximately every four months (www.fda.gov); the

register should not assume either cadence.

2. **Ingest** each Federal Register notice. Notices appeared on 2 October (public-inspection.federalregister.gov), 21 November (public-inspection.federalregister.gov) and 5 December 2025 (public-inspection.federalregister.gov), then on 27 February (public-inspection.federalregister.gov), 29 July (www.govinfo.gov) and 24 August 2026, with 22 May 2026 as the intervening reference (public-inspection.federalregister.gov). The July notice contained only revised guidances, all for injectable peptide products, in what a consulting firm called an unusual posting (www.lachmanconsultants.com), so revision-only batches can arrive off cycle.
3. **Match** each guidance record to products using the join rule in Table 3.
4. **Assess** each match against Table 2, recording the lifecycle state.
5. **Escalate** flagged cells to a specialist, and to FDA where a documented route exists.
6. **Approve** the decision with a named approver. Consulting firms advise the same pattern: scan the new and revised list carefully (www.lachmanconsultants.com), and contact FDA to determine the impact of a revision that changes BE requirements (www.lachmanconsultants.com).

Exception handling should cover four cases, and in each the default is to hold the item open with the source text attached, not to close it by inference.

- **Unmatched join:** the product cannot be tied to an application number, route, form and strength; route to a specialist queue.
- **Source mismatch:** the announcement and the PDF differ, as in the TWYNEO example; record both and ask FDA or a specialist.
- **Moved or missing plan:** a planned row changes date or never appears; keep the plan record open and note the list update date.
- **Ambiguous category:** the revision text does not clearly fit the FDA definitions; treat it as the higher category until a specialist decides.

Workload planning can use a user-supplied formula: review workload equals affected protocols multiplied by estimated review hours per protocol. (Hypothetical Example) A sponsor that matches six protocols to flagged cells, estimating eight review hours each, would carry 48 specialist hours; at four hours each it would carry 24. The inputs are invented for illustration, are not a benchmark, and say nothing about study cost or savings.

Data Analysis and Evidence

The quantitative record is compact, and most of it comes from FDA documents. The figures do not share a common unit, so they are presented as labeled paragraphs rather than a table.

Batch composition. The August batch had 55 PSGs: 24 new and 31 revised (www.fda.gov). Of the 55, 18 were for complex products (7 new, 11 revised). That is about one third (18 of 55, by simple division). The 31 revised PSGs are individually unclassified in the announcement; the Federal Register tables list active ingredients only (public-inspection.federalregister.gov), so category counts for the batch are unknown from the sources reviewed.

Look-ahead list. As of the 21 August 2026 update (www.fda.gov), the new-PSG table had 58 entries (www.fda.gov) and the revised table 32 (www.fda.gov). These are row counts of application and form records. They should not be added to the 55 PDFs in the batch or to each other as a pipeline estimate, because rows can repeat across tables and because the page removes issued items on each update. Some entries carry only a coarse window such as "Within the next 12 months" (www.fda.gov) or "Beyond 12 months" (www.fda.gov), and others note a move to an earlier date (www.fda.gov) or a later one (www.fda.gov).

November 2026 plans. The displayed rows included planned November 2026 items, for example an in vitro option addition for an ophthalmic suspension (www.fda.gov). As of 20 October 2026 the page still showed its 21 August update, and November had not begun. Whether each planned November item is issued cannot be assessed yet; each stays "planned, not issued" until a PDF and Federal Register notice appear.

Revision waves can be large. FDA's FY 2025 report states that it issued 925 PSGs, 49 of them for complex products (www.fda.gov). It attributes most of the volume to M13A implementation, in which more than 826 draft PSGs were revised (www.fda.gov), with the revised PSGs recommending one BE study, under either fasting or fed conditions, for products with a non-high risk of bioinequivalence due to food effect, rather than two studies (one fasting and one fed) (www.fda.gov). By simple division, 826 of 925 is about 89 percent. The cumulative stock moved from 2,223 PSGs at the end of FY 2024 (www.fda.gov) to 2,288 at the end of FY 2025 (www.fda.gov), a net rise of 65. FY 2024 issuance had been 206 (www.fda.gov). The lesson for registers is that "issued" counts can reflect re-issuance of existing PSGs, so volume is not a measure of new product coverage. The wave followed the International Council for Harmonisation (ICH) M13A guideline on immediate-release solid oral BE, adopted on 23 July 2024 (database.ich.org). Another ICH document in the series, M13B on additional-strength waivers, was adopted on 4 August 2026 (database.ich.org). No source reviewed ties M13B to planned PSG revisions, so it is a watch item, not a forecast.

Engagement uptake. The FDA-TRACK workbook lists two PSG teleconference requests submitted across October 2025 to August 2026 and none for pre-submission or post-submission PSG meetings in that period; these are submitted requests, not confirmed meetings held (www.fda.gov). The month placement is inferred from column headers, so the safe reading is a cumulative count of two submitted requests. The data do not show how many sponsors were eligible, so no uptake rate can be calculated, and they do not show why so few requests were submitted.

Published peer-reviewed context. A 2023 review by FDA authors reports that PK endpoint BE studies account for 88 percent of the BE approaches recommended in PSGs for solid oral immediate-release products (pmc.ncbi.nlm.nih.gov), and cites an estimate that PSG availability could reduce a developer's expected capitalized costs by 22.3 percent (pmc.ncbi.nlm.nih.gov). That estimate concerns PSG availability in general and is not a statement about the cost of a revision. A 2025 paper notes that PSG recommendations may include in vitro characterization, PK endpoint studies and comparative clinical endpoint studies (pmc.ncbi.nlm.nih.gov), and documents a revision in which the dapstone topical gel PSGs, revised in February 2024 (pmc.ncbi.nlm.nih.gov), no longer included an in vitro permeation test or PK study in one option (pmc.ncbi.nlm.nih.gov). Revisions therefore can reduce evidence burden as well as add to it.

International comparison. The European Medicines Agency (EMA) states that its product-specific BE guidelines must be read together with ICH M13 (www.ema.europa.eu), after M13A formally superseded applicable parts of its earlier BE guideline (www.ema.europa.eu), and publishes a forward list of expected

guidelines (www.ema.europa.eu). A paper by EMA-affiliated authors notes that EMA undertakes public consultation where BE requirements have changed (pmc.ncbi.nlm.nih.gov). Health Canada implemented M13A on 27 December 2025 (www.canada.ca). M13A itself leaves regulatory decision-making out of scope (database.ich.org), which is why regional product-level recommendations still need separate tracking.

No benchmark of review hours, time savings or approval-rate effects of PSG revisions was found in the sources reviewed, and none is asserted.

Implications and Future Directions

For the next planned batch. FDA's list indicates additional revision activity in November 2026 and later, with minor revisions prominent in the rows visible. A versioned assessment prepared now can be re-run against the actual PDFs when they appear, with the planned row closed and the PDF record opened. Because planned dates move, no internal deadline should be pegged to a planned month.

For regulatory information systems. The register in Table 3 is deliberately small. It can be built in a regulatory information management system, a validated spreadsheet or a controlled database. The design choice that matters is immutability: source text, hashes and approvals should be append-only so that an auditor can see which PSG version informed which decision. An adjacent advisory firm such as IntuitionLabs can help teams design the process, but the control content here derives entirely from FDA's published language and should be validated by the sponsor's own specialists.

For FDA engagement design. The documented engagement routes cluster around signed in vivo protocols and submitted ANDAs. An FDA-posted draft goals letter for FY 2028 to 2032 proposes a meeting type for clarifying the impact of a PSG change on an ongoing ANDA program (www.fda.gov). That document describes a future program, not current policy, and should not be used to plan 2026 submissions.

For monitoring scope. Sponsors that file outside the United States face parallel changes. EMA's practice of consultation before finalization (pmc.ncbi.nlm.nih.gov) and Health Canada's M13A date (www.canada.ca) show that a single molecule can carry several jurisdiction-specific recommendations, and each needs its own register row.

Open questions. Several items remain unknown from the sources reviewed, and each should be asked of FDA or a specialist, not assumed.

- **Batch categories:** the category of each of the 31 revised PSGs in the August batch.
- **TWYNEO option:** the mismatch between the announcement and the PDF text.
- **List contents:** the upcoming list beyond the displayed rows.
- **Effective dates:** any FDA statement of effective dates for revised PSGs.

Frequently Asked Questions (FAQs)

What are FDA product-specific guidances for generic drug development?

They are FDA's recommendations on how to develop a generic product therapeutically equivalent to a specific reference listed drug, described by the agency as its current thinking and expectations (www.fda.gov). When final, they remain guidance, which does not legally bind the public or FDA.

How do I track FDA PSG revisions?

Snapshot the upcoming list each time it changes, ingest Federal Register notices, and compare each retrieved PDF against its stored hash. FDA's guidance search page also offers email updates on recently issued guidances (www.fda.gov), but that general mechanism was not verified here as covering PSG revisions specifically.

What is the FDA product-specific guidance new and revised batch?

The most recent batch, released on 21 August 2026, contained 55 draft PSGs, 24 new and 31 revised. The next planned items appear on the upcoming list, with timing subject to change.

Does a revised PSG change a bioequivalence study that has already started?

Not automatically. FDA offers a PSG teleconference to applicants whose in vivo study protocol was signed before the PSG publication date, and only when the new or revised PSG introduces or revises an in vivo BE recommendation; limited discretionary post-submission exceptions exist for certain ANDA applicants. A signature alone does not establish eligibility. The outcome depends on the revision category and the specific program, and requires specialist assessment and FDA feedback.

How does a PSG revision affect pending ANDA submissions?

FDA's commitment letter says division-level leadership will be made aware of potential impact on pending ANDAs (www.fda.gov). A post-submission PSG teleconference is available once the ANDA is submitted and an in vivo study has been commenced or completed, though FDA recommends waiting during an assessment cycle until after a discipline review letter or complete response letter (www.fda.gov).

What is the GDUFA product-specific guidance timeline?

For requests that are granted under the applicable criteria, FDA commits to hold a PSG teleconference within 30 days of receipt of the request, and to schedule pre-submission meetings within 120 days (www.fda.gov) and post-submission meetings within 90 days (www.fda.gov). The standard original ANDA goal is action within 10 months for 90 percent of applications (www.fda.gov).

How should in vitro bioequivalence study design be handled when a PSG changes?

Read the exact PSG text, treat any added in vitro option as a minor revision under FDA's definition, and seek feedback through a pre-ANDA meeting where the PSG recommends it (www.accessdata.fda.gov). The TWYNEO example shows why the announcement and PDF should be compared before relying on an option.

Is a draft revised PSG the same as a final recommendation?

No. FDA states that it considers comments before finalizing, and the Federal Register notice says it either publishes final guidances or revised drafts afterward (public-inspection.federalregister.gov).

Conclusion

A PSG revision is a change to a source document, and the right response depends on what FDA actually published, in what form, and where each program sits. The August 2026 batch of 55 draft PSGs and the list of planned revisions (www.fda.gov) give sponsors two different kinds of evidence: published draft recommendations and plans that may move. Keeping those apart, counting PDFs separately from list rows, and preserving original wording and source version are the core controls.

The category-by-stage matrix directs attention to the places FDA has documented a route: signed in vivo protocols, submitted ANDAs, and approved applications under a critical revision. Elsewhere it directs internal assessment by a specialist. The register schema makes each decision traceable to a source version and a named approver, and the TWYNEO example shows the cost of skipping that step: an announcement and a PDF can read differently, and the register should hold both until FDA or a specialist resolves it.

Several limits apply. The sources reviewed document no automatic obligation for most combinations, no prior versions of the example PSG were available, the full upcoming list and the PSG database could not be read in full, and no benchmark of workload or savings exists. Teams should treat this report as a design for a register and a set of questions to put to FDA and to qualified specialists, not as advice on any specific product.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://www.fda.gov/drugs/drug-alerts-and-statements/fda-publishes-new-product-specific-guidances-facilitate-generic-drug-development>
2. <https://www.federalregister.gov/public-inspection/2026-17222/draft-and-revised-draft-guidances-product-specific-guidances>
3. <https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development>
4. <https://www.ecfr.gov/api/render/v1/content/enhanced/current/title-21?section=10.115>
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10. <https://resource.ddregpharma.com/blogs/searchable-databases-for-bio-equivalence-guidance>
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45. <https://www.fda.gov/media/194166/download>
46. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

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