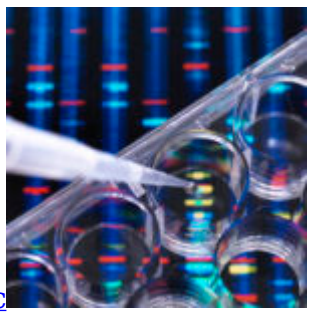
FDA Proposes Phased Approach to Regulating Laboratory Developed Tests

On September 29, 2023, the U.S. Food and Drug Administration (FDA) posted and scheduled for publication its long-awaited **proposed rule** concerning FDA regulation of laboratory developed tests (LDTs). If enacted, the proposed rule would amend the Agency's regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act; and this includes when the manufacturer of the IVD is a laboratory.

Upon finalization of the rule, FDA proposes to phase out its general "enforcement discretion" approach for LDTs so that tests manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs.

Comments to the proposed rule are due 60 days after the date of publication of the proposed rule in the Federal Register. We will provide our full analysis of the proposed rule in the coming days. Contact the authors or a member of the Goodwin **Life Sciences Regulatory & Compliance** team for any questions.

Bloomberg Intelligence – Arman Oruc's Perspective on the FTC and Pharma and Biotech Industry M&A Impact

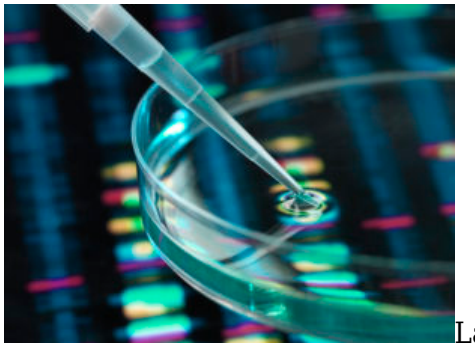


Arman Oruc joined the **Bloomberg Intelligence** podcast to share his views

on the FTC, and its impact on M&A for the pharma and biotech industry.

Listen to the podcast **here**.

Is it Biosimilar or Interchangeable? It Won't Be Easy to Tell Under FDA's Latest Draft Labeling Guidance



Last week, **FDA released** a draft guidance, "**Labeling for Biosimilar and Interchangeable Biosimilar Products**" that—when finalized—will revise and replace its July 2018 final guidance, "**Labeling for Biosimilar Products**." FDA noted that this 2023 Draft Guidance reflects recommendations based on the "valuable experience about labeling considerations" that FDA has gained through its approval of 42 biosimilar products, including four interchangeable biosimilar products.

Notably, the 2023 Draft Guidance provides further recommendations regarding when to use a biosimilar or interchangeable biosimilar product name, and when to use the reference product name in labeling:

- The biosimilar or interchangeable biosimilar product's proprietary name[1] (or if the product does not have a proprietary name, its proper name[2]) should be used when –
    - Information in the labeling is *specific to the biosimilar (or interchangeable biosimilar) product*, including such references to the product in the INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, DESCRIPTION, and HOW SUPPLIED/STORAGE AND HANDLING sections, and/or
    - For "directive statements and recommendations for preventing, monitoring, managing, or mitigating risk," including such references to the product in the BOXED WARNING, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and DRUG INTERACTIONS sections.

- When referring to the *drug substance* in the labeling, the biosimilar or interchangeable biosimilar product's proper name should be used.

- When information *specific to the reference product* is described in the biosimilar or interchangeable biosimilar product's labeling (for example, data from clinical trials of the reference product in the ADVERSE REACTIONS and CLINICAL STUDIES sections), the reference product's proper name should be used.

- In sections of the labeling containing *information that applies to both the biosimilar (or interchangeable biosimilar) product and the reference product*—such as BOXED WARNING, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS—the labeling should use the core name of the reference product followed by the word "products."[3]

FDA acknowledges that the application of these recommendations is highly context-dependent and may not always be clear, but recommends that biosimilar and interchangeable biosimilar product sponsors evaluate all statements in product labeling carefully to determine the most appropriate product identification approach in each instance.

Another noteworthy aspect of the 2023 Draft Guidance is the Agency's recommendation regarding the biosimilarity statement and footnote in the HIGHLIGHTS section of a biosimilar or interchangeable biosimilar product's labeling.[4] Previously, FDA recommended a biosimilarity statement for a biosimilar product and an interchangeability statement for an interchangeable biosimilar product. The 2023 Draft Guidance now recommends a statement and footnote in the HIGHLIGHTS section that the product is biosimilar to the reference product, *regardless of* whether the product is a biosimilar or an interchangeable biosimilar to the reference product. In the **Federal Register notice** announcing the 2023 Draft Guidance, FDA acknowledges that this marks an "evolution in our thinking" and explains that "a labeling statement noting that certain products within a 351(k) [Biologics License Application] have been approved as interchangeable, and explaining the interchangeability standard, is not likely to be useful to prescribers, who can prescribe both biosimilar and interchangeable biosimilar products in place of the reference product with equal confidence that they are as safe and effective as their reference products." FDA further states that "information about interchangeability is more appropriately located in the Purple Book rather than labeling."

Other notable elements of the 2023 Draft Guidance include recommendations regarding how to describe pediatric use data in a range of scenarios and how to incorporate immunogenicity data. With respect to immunogenicity data, the 2023 Draft Guidance suggests that a contextual paragraph[5] generally be included in the relevant CLINICAL PHARMACOLOGY subsection before describing the available immunogenicity data for the reference product and the biosimilar or interchangeable biosimilar product. The 2023 Draft Guidance also outlines the Agency's expectations for patient labeling—such as a Medication Guide, Patient Information, or Instructions for Use—for a biosimilar or interchangeable biosimilar product, if the reference product has such patient labeling.

Information on how to submit comments on the 2023 Draft Guidance can be found at **https://www.regulations.gov/docket/FDA-2016-D-0643.**

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[1] The proprietary name of a biosimilar product is a brand name determined by the sponsor. The fictitious example provided in the 2023 Draft Guidance is "NEXSYMEO."

[2] The proper name of a biosimilar product is the nonproprietary name designated by FDA that consists of a biological product's core name plus a unique four-letter suffix. The fictitious example provided in the 2023 Draft Guidance is "replicamab-cznm."

[3] The fictitious example provided by FDA in the 2023 Draft Guidance is "replicamab products".

[4] The fictitious example provided by FDA in the 2023 Draft Guidance is "NEXSYMEO (replicamab-cznm) is biosimilar* to JUNEXANT (replicamab-hjxf)" and the accompanying footnote is "Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of *[BIOSIMILAR OR INTERCHANGEABLE BIOSIMILAR PRODUCT'S PROPRIETARY NAME]* has been demonstrated for the condition(s) of use (e.g.,

indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration) described in its Full Prescribing Information."

[5] The Agency's suggested paragraph is, "The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of [*proper name of reference product*] or of other [*core name*] products."

Modernizing the FDA's 510(k) Program for Medical Devices: Selection of Predicate Devices and Use of Clinical Data in 510(k) Submissions

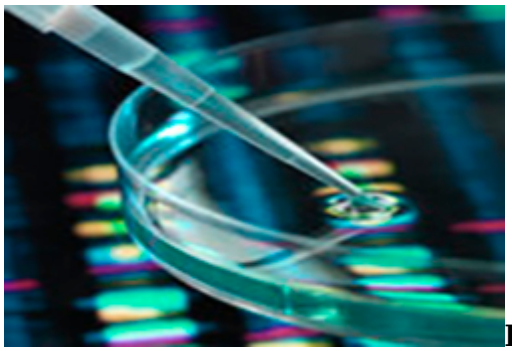
On September 6, 2023, the US Food and Drug Administration (FDA) released a trio of draft guidances in its efforts to "strengthen and modernize" the 510(k) Program and provide for more "predictability, consistency, and transparency" for the 510(k) premarket review process. In this post, we discuss the two new draft guidances with broad applicability to the 510(k) Program:

- "**Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission**"
- "**Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions**"

The two draft guidances address a number of fundamental issues of concern with the 510(k) process.

Read the full client alert **here**.

UK's Medicines Regulator Announces Guidance on the New International Recognition Procedure for the Approval of New Medicines from 1 January 2024



Background

Earlier this year, the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), announced that a new International Recognition Procedure (IRP) will be put in place for the approval of new medicines from 1 January 2024. On 4 September 2023, the MHRA announced the publication of detailed **guidance** on this new procedure, which will replace the **European Commission Decision Reliance Procedure** (ECDRP). The **Decentralised and Mutual Recognition Reliance Procedure** (MRDCRP), which allows the MHRA to have regard to approvals in the EU through the decentralised and mutual recognition procedures, will be incorporated under the umbrella of the IRP.

European Commission Decision Reliance Procedure

The ECDRP was introduced post-Brexit as a temporary measure to try and ensure continued access to new medicines from the EU for patients in Great Britain until 31 December 2023.

Under the ECDRP, the MHRA may rely on a decision taken by the European Commission on the grant of a new marketing approval in the EU through the centralized procedure, in order to grant a new marketing approval in Great Britain more quickly.

International Recognition Procedure

From 1 January 2024, the MHRA will have regard to decisions already made by medicines regulators in Australia, Canada, the European Union, Japan, Singapore, Switzerland and the United States (Reference Regulators).

The IRP will be open to applicants that have already received a marketing approval for the same product from one of the MHRA's specified Reference Regulators. The MHRA defines "same product" as "*as having the same qualitative and quantitative composition (active substance(s) and excipients), and the same pharmaceutical form, from applicants belonging to the same company or group of companies or which are licensees.*"

There are two procedures that can be used for initial applications for a new marketing approval using the IRP:

- **Recognition A** – applications under this procedure will be approved within 60 days (excluding

clock stops), unless there are any major objections which cannot be resolved within 60 days. If this occurs, the timetable may revert to Recognition B. To qualify for this procedure, the Reference Regulator must have given approval for the product within the last two years, the manufacturing process must be unchanged and the product must not meet any of the 24 listed conditions of Recognition B.

- **Recognition B** – applications under this procedure will be approved within 110 days (excluding clock stops), unless there are any major objections at day 110. If this occurs, the timetable will then revert to 210 days and formal advice from the Committee for Medicinal Products for Human Use will be sought on approvability. To qualify for this procedure, the Reference Regulator must have given approval for the product within the last ten years, and at least one of 24 listed conditions must apply. The conditions include if the product is: (i) designated as an orphan medicinal product in Great Britain, (ii) an advanced therapy medicinal product, (iii) a cutting-edge technology, or (iv) a first-in-class active substance.

Practical Implications

The IRP will allow the MHRA to take into account the expertise and decision-making of trusted medicines regulators when approving a new medicine from 1 January 2024.

It is unclear if there are any specific requirements for choosing the Reference Regulator if the product is approved by more than one eligible medicines regulator.

As a final note, the IRP will sit alongside the MHRA's current national procedures. Any ECDRP and MRDCRP applications for marketing approval received by the MHRA *after* 1 January 2024 will be assessed under the new IRP. Any ECDRP and MRDCRP applications for marketing approval received by the MHRA *before* 31 December 2023 will be assessed under the current ECDRP and MRDCRP respectively.

PropSci Perspectives: Breakthrough Properties

The Goodwin **Propsci** team has partnered with several well-known companies for a short video series that explores what's happening in the real estate life sciences industry.

In our latest installment, Susie Harborth, Chief Business Officer at Breakthrough Properties, joins **Nicole Riley** for a thought-provoking discussion. Breakthrough Properties is a life sciences real estate development company that leverages cross-sector collaboration to deliver environments that foster innovation and scientific breakthroughs.

Watch the video **here**.