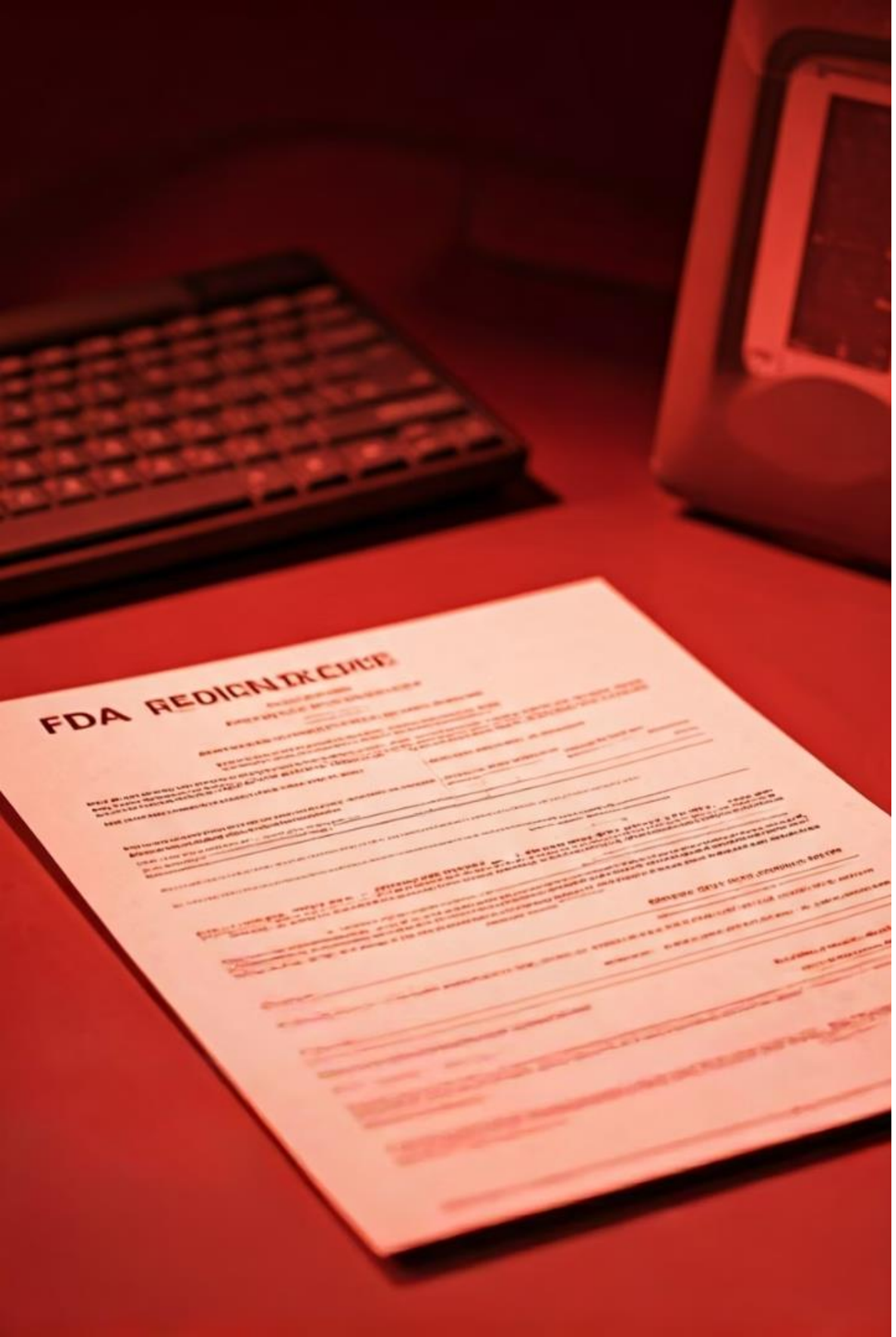

User Fees and Refunds for Premarket Notification Submissions (510ks)

By Amrutha Rai, Team Lead, FDA Regulations

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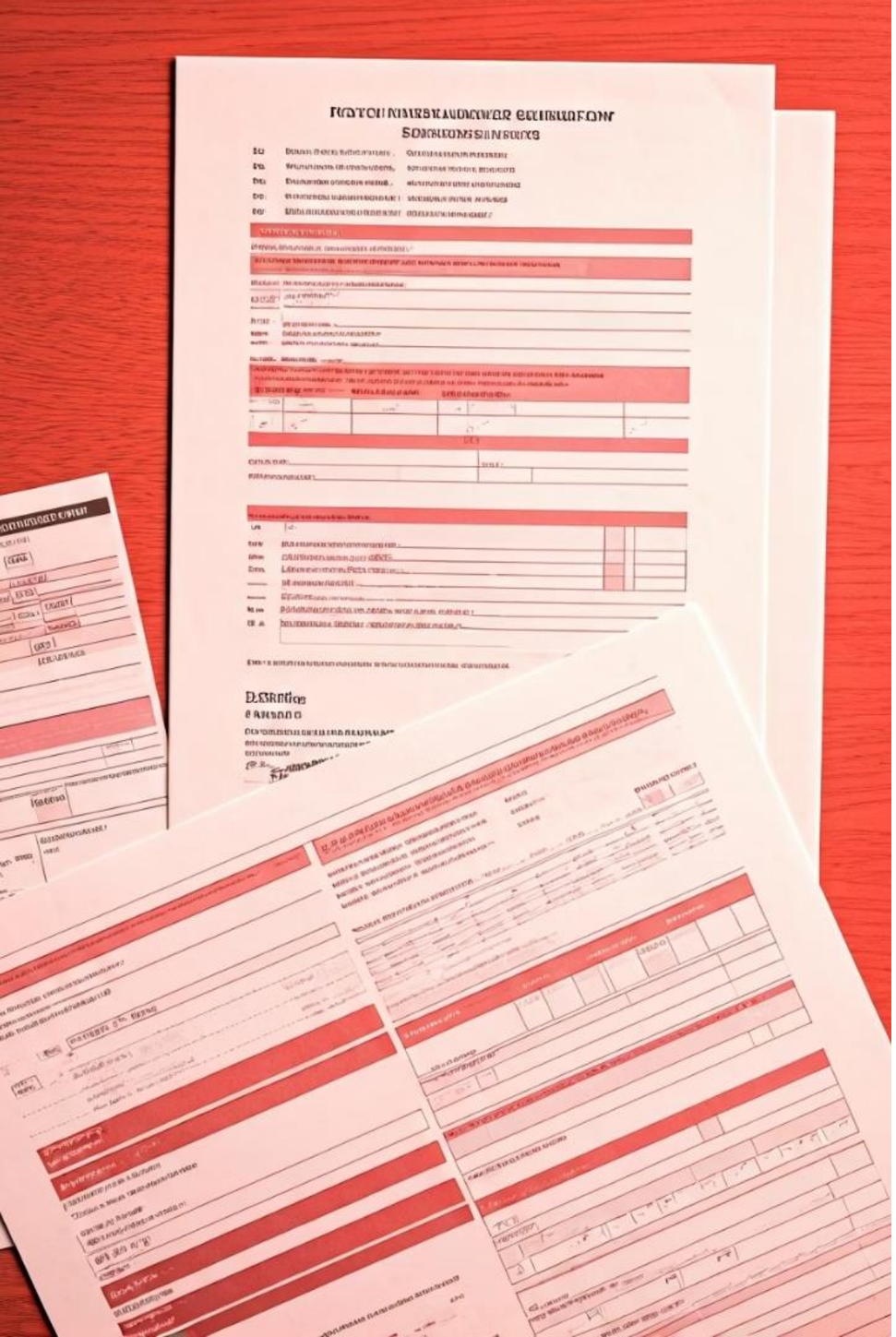


Types of 510(k) Submissions Subject to User Fees

Traditional 510(k)s

Standard submissions that include all required elements for FDA review.

Abbreviated 510(k)s

Submissions that utilize guidance documents, special controls, or recognized standards.

Special 510(k)s

Submissions for modifications to a manufacturer's own legally marketed device.

All 510(k) submissions are subject to user fees except those reviewed by FDA-accredited third parties, submissions for devices intended solely for pediatric populations, and submissions by state or federal government entities (unless the device will be commercially distributed).

Exemptions from User Fees

Third Party Reviews

510(k)s reviewed by FDA-accredited third parties pursuant to section 523 of the act are exempt from user fees. Similarly, FDA does not assess fees for 510(k)s reviewed by European Union Conformity Assessment Bodies (EU CABs), as they serve the same function as FDA-accredited third parties.

Pediatric Devices

Submissions for devices intended solely for pediatric populations are exempt from user fees. If FDA determines during review that a submission qualifies for this exemption (even if the manufacturer did not request a waiver), the agency will refund the user fee.

Government Entities

510(k)s submitted by state or federal government entities are exempt from user fees, unless the device will be commercially distributed. If a fee is mistakenly submitted with any of these types of 510(k)s, FDA will refund it.

Refunds for 510(k) Submissions

Not a Device

FDA will refund user fees for submissions that are not required because the agency determines that a product is not a device under regulatory definition.

Exempt by Regulation

Refunds will be provided if there is a classification regulation that exempts the device from 510(k) review. However, if the device exceeds the limitations to exemption, a new 510(k) and user fee would be required.

Pediatric Determination

If FDA determines that a submission qualifies for the pediatric exemption although the manufacturer did not request a waiver, the agency will refund the user fee.

FDA encourages manufacturers to review classification regulations and consult with agency personnel before submitting 510(k)s for products that may not require review. This helps conserve both FDA and industry resources. Manufacturers may also obtain information regarding the regulatory status of their device by submitting a request under section 513(g) of the act, which has no associated user fees.

Non-Refundable Scenarios

Withdrawn Submissions

FDA will not refund user fees for 510(k)s that are withdrawn by the submitter

Failure to Respond

No refund if FDA considers a submission withdrawn due to failure to supply requested information

NSE Determinations

No refund for any Not Substantially Equivalent determination, regardless of reason

The agency does not refund fees for withdrawn submissions because significant resources are typically already expended on review at the time of withdrawal. This is consistent with MDUFMA provisions, which anticipate the possibility of refunds for withdrawn PMAs but create no similar provision for 510(k) withdrawals. If a 510(k) is withdrawn and later resubmitted, FDA will assess the fee in effect at the time of the new submission.

Fees for Resubmissions After NSE Determination

New 510(k) Submission

If you submit a new 510(k) with additional data showing your device is substantially equivalent, FDA will assess the 510(k) fee in effect at the time of submission.

De Novo Petition

If your device is found NSE because no predicate exists or it has a new intended use, you may petition for de novo classification under section 513(f)(2)(A) of the act. No user fee is required.

PMA Submission

If you submit a Premarket Approval application, FDA will assess the PMA fee in effect at the time of submission.

HDE Application

Humanitarian Device Exemption applications are not subject to user fees.

Any new submission for a device previously found NSE is subject to the fee associated with the submission type, if that type is subject to fees. The appropriate pathway depends on the reason for the NSE determination.

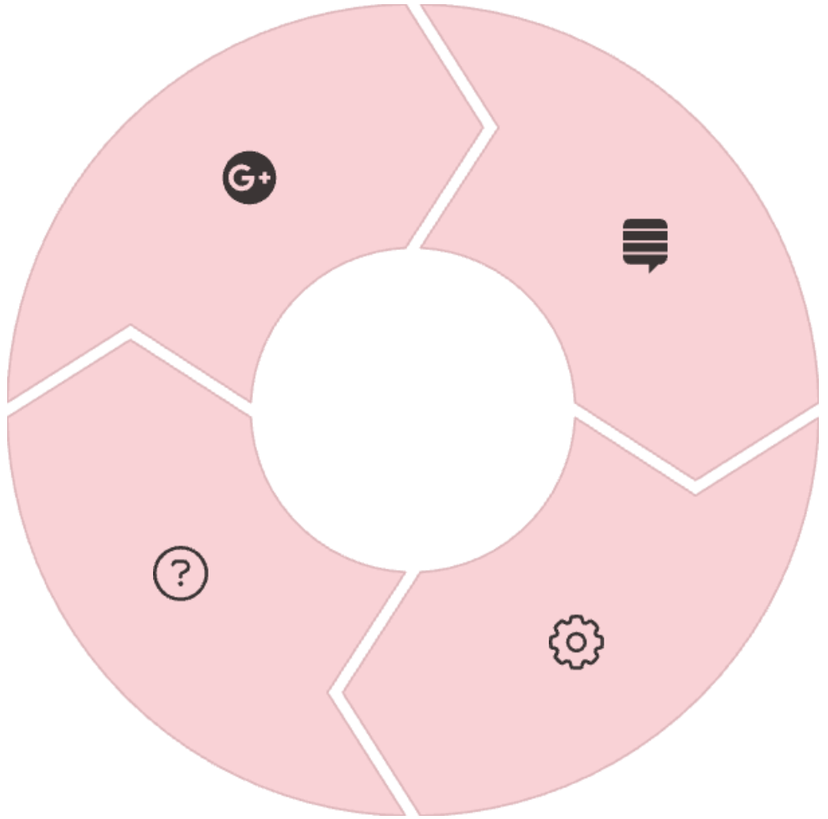
Additional Information and Modifications

Additional Information

No fees when submitting additional information to a pending 510(k) for which FDA has not yet rendered a final decision

Pre-Submission Consultation

Consultation with FDA before submitting 510(k)s can help determine if review is necessary



New Indications

New 510(k) and fee required if submitting unsolicited information that constitutes a new indication for use

New Technology

New 510(k) and fee required if submitting unsolicited information that constitutes new technology

FDA encourages manufacturers who intend to modify a legally marketed device to consult the guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." This helps determine whether the change requires a new 510(k) submission. The agency will not refund user fees if a manufacturer later decides that a change may not have required a new 510(k) and wishes to withdraw the submission.

Summary of Fees and Contact Information

Submission Type	Fee Required
Original 510(k) Submission	Yes
510(k) Reviewed by Third Party	No
510(k) for Pediatric Population	No
510(k) from Government Entity	No
Device Previously Found NSE	Yes
Additional Information for Pending 510(k)	No

For questions regarding submissions to the Center for Devices and Radiological Health, contact at 240-276-4021 or by email at heather.rosecrans@fda.hhs.gov. For questions regarding submissions to the Center for Biologics Evaluation and Research, contact at 301-827-0373 or by email at wilsonl@cber.fda.gov.

Additional copies of this guidance are available from the FDA website at http://www.fda.gov/cdrh/mdufma/guidance/1511.pdf or http://www.fda.gov/cber/mdufma/mdufma.htm.