

4.3 – APPENDIX C: ALLOWABLE AND EXCLUDED COSTS FOR THE MDUFA PROGRAM

Introduction

The FD&C Act, as amended, defines the process for the review of device applications and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. Using the statutory definition and the methodologies described in Appendix D, the Agency identified those activities that were applicable to the MDUFA program.

MDUFA Program Costs

Included Activities

Section 737(8)(A) - *The activities necessary for the review of PMAs, PMRs, supplements, and premarket notification submissions. These activities include, but are not limited to, the following:*

- 510(k)s -- Traditional/Supplements/Abbreviated/Specials (third-party and non-third-party);
- Evaluation of Automatic Class III Designations;
- Traditional and Priority Review PMAs (includes amendments, supplements, and annual reports);
- Modular PMAs (shell, modules, amendments, supplements, and annual reports);
- PDPs (including amendments, supplements, and annual reports);
- Premarket Reports (amendments, supplements, and annual reports);
- Reclassification Petitions;
- Class II Exemption Petitions;
- BLAs and BLA Supplements (applications subject to 351 of the PHS Act);
- Recruitment and use of outside experts during the review process;
- Obtaining advisory committee input (e.g., convened meetings, homework assignments);
- Resolution of product jurisdictional issues;
- Dispute resolution/appeals;
- IT support for review activities; and
- Recruitment of review staff.

Section 737(8)(B) - The issuance of action letters that allow marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval. This includes activities such as the issuance of deficiency letters, meetings with applicants to discuss such letters, and review of the responses.

Section 737(8)(C) - The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements. This would include activities such as the review of manufacturing information submitted in PMAs, pre-approval current good manufacturing practices (GMP) inspections, and resolution of any identified GMP issues.

Section 737(8)(D) - Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions. For the types of applications identified above, this would include monitoring activities such as:

- conduct of bioresearch monitoring inspections (both “for cause” and pre-approval) of sponsors, institutional review boards, and clinical investigators;
- adverse event and complaint investigations related to ongoing clinical trials; and
- Good Laboratory Practice inspections (21 CFR Part 58).

Section 737(8)(E) - Review of device applications subject to section 351 of the Public Health Service Act for an Investigational New Drug application (IND) under section 505(i) or for an IDE under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) and 520(g). This would include the review of the IDEs (original, amendments, and supplements) and INDs (amendments, supplements, and safety reports). Also included are pre-IDEs (review of the submission and any meetings or correspondence), significant/non-significant risk determinations, and Determination/Agreement meetings.

Section 737(8)(F) - The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions. This would include activities such as the development of device-specific, cross-cutting, special control, and program-related guidances as well as “Blue Book Memoranda” and Standard Operating Procedures.

Section 737(8)(G) - The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of applications, reports, supplements, or submissions and related activities. This would include national and international standards development and coordination related to the review of premarket applications.

Section 737(8)(H) - The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

This would include activities such as:

- informal consultation via phone, meetings, e-mail, and facsimile;
- meetings between FDA and applicants, such as pre-submission meetings, Determination/Agreement meetings, and meetings to discuss deficiencies in premarket applications;
- use of outside experts in the review of premarket applications;
- review of labeling prior to approval of a premarket application or supplement;
- FDA-sponsored conferences/workshops related to premarket submissions; and
- staff participation at non-FDA meetings related to such applications.

Section 737(8)(I) - Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device. *This would include activities such as the review of requests for information submitted under section 513(g) and the “call” for PMAs for pre-amendment devices.*

Section 737(8)(J) - Evaluation of postmarket studies required as a condition of approval of a premarket application or premarket report under section 515 or section 351 of the PHS Act. *This would include activities such as the review of:*

- protocols for the post-market studies;
- modifications to such protocols;
- data collected under the protocol; and
- labeling changes (instructions for use, warnings, precautions, etc.), if needed as a result of the review of the data.

Section 737(8)(K) - Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

This would include activities such as:

- epidemiology studies; and
- post-marketing problem identification/resolution, including reports filed under the Medical Device Report regulation.

Training related to premarket and post-market approval activities. *This would include the following types of training:*

- scientific, clinical, and statistical training;

- managerial or other administrative training;
- policy/regulatory training;
- professional development (coursework, attendance at professional meetings, library resources);
- “Vendor Days;” and
- Site Visit Program for premarket reviewers.

User Fee Act implementation. This would include activities such as:

- guidance/regulation development;
- stakeholder outreach for educational and comment purposes;
- training of agency staff; and
- IT support for implementation.

All user-fee-related costs represented by the above activities are collectively referred to in this report as costs for the MDUFA program.

Section 737(9) of the FD&C Act defines the "costs of resources allocated for the process for the review of device applications" as the expenses in connection with this process for:

- A. officers and employees of FDA, FDA contractors, advisory committees, and costs related to such officers, employees, committees, and to contracts with such contractors;
- B. management of information, and the acquisition, maintenance, and repair of computer resources;
- C. leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and
- D. collecting user fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

Excluded Activities

- enforcement policy and regulation development;
- third-party inspection program;
- post-approval compliance actions and activities unrelated to PMA Conditions of Approval and investigations of safety and effectiveness issues for devices subject to FDA regulation;
- post-approval activities relating to:

- promotion and advertising;
- international coordination/Mutual Recognition Agreement work;
- international standards development;
- liaison/outreach and manufacturing assistance;
- device tracking;
- inspections unrelated to the review of covered applications;
- export/import activities unrelated to the conduct of a clinical trial;
- research related to future products; and
- all activities conducted under the Mammography Quality Standards Act (MQSA), radiation safety authorities of the FD&C Act (sections 531 et seq.), and the Clinical Laboratory Improvement Amendments of 1988 (CLIA).