Overview of the Change Request for OMB Control No. 0910-0120

Change Request (83-C)

November 22, 2019

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) as result of publication of the final rule, "Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies to be Allowed in Electronic Format". The rule will remove requirements to submit multiple paper copies of medical device regulatory pre-submissions and submissions and replace them with one copy in an electronic format. We are revising the applicable premarket submissions and registration and listing regulations to make an efficient and effective electronic submission program, including those submissions in these information collections:

The final rule will amend regulations for the following submission types:

- 0910-0120 -- Premarket Notification (510(k)) submissions (21 CFR 807.90), including confidentiality of Information certifications (21 CFR 807.95);

- 0910-0078 -- Investigational Device Exemption (IDE) applications (21 CFR 812.20);

- 0910-0231 -- Premarket Approval Applications (PMAs) (21 CFR 814.20), including PMA supplements (21 CFR 814.39); and

- 0910-0332 -- Humanitarian Device Exemption (HDE) Applications (21 CFR 814.104).

These amendments will not make any substantive changes to specific data elements within the information collection, but respondents may realize a monetary savings from administrative expenses associated with the preparation and mailing of paper submissions currently provided for in the regulations. Submissions are, on average, hundreds of pages long, and some are much longer.[1] Such submissions are costly to print and ship.

Currently, firms must mail multiple eCopies to FDA for multiple types of medical device premarket pre-submissions and submissions. The amendments will reduce the number of electronic copies required for many submission types, eliminating the need to produce multiple eCopies. As a result, firms will benefit from reduced costs for eCopy media.

Table 1. Current Requirements for Device-Related Submissions

Submission Type	Number of Full Paper Copies Required	Number of eCopies Required
Premarket Notifications (510(k)s)	1	1
Original Premarket Approvals (PMAs) and Humanitarian Device Exemptions (HDEs)	1	5
Panel-Track Supplements[a]	1	5
180-Day Supplements[a]	1	5
Real-Time Supplements[a]	1	2
30-Day Notices[a]	1	2

[1] The average original PMA submitted in 2018 was over 25,000 pages long.

135-Day Supplements[a]	1	2
Annual Reports[a]	1	1
Post-Approval Study Reports[a]	1	1
Modular PMAs or HDEs	1	2
Average over All Types of PMAs or HDEs	1	2.78
Investigational Device Exemptions (IDEs)	1	2

[a] Indicates a supplement, report, or notice for a PMA or HDE.

Table 2. New Requirements for Device-Related Submissions

Submission Type	Number of Full Paper Copies Required	Number of Copies in Electronic Format Required
510(k)s	0	1
Original PMAs and HDEs	0	1
Panel-Track Supplements[a]	0	1
180-Day Supplements[a]	0	1
Real-Time Supplements[a]	0	1
30-Day Notices[a]	0	1
135-Day Supplements[a]	0	1
Annual Reports[a]	0	1
Post-Approval Study Reports[a]	0	1
Modular PMAs or HDEs	0	1
Average over All Types of PMAs or HDEs	0	1
IDEs	0	1

[a] Indicates a supplement, report, or notice for a PMA or HDE.