UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Devices Current Good Manufacturing Practice;
Quality System Regulation – 21 CFR Part 820

OMB Control Number 0910-0073

**Non-substantive Change Request to an existing information collection:**

*Background –*

This information collection supports regulations in 21 CFR part 820, which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in part 820 are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). The regulations set forth basic provisions applicable to manufacturers of finished medical devices, including recordkeeping and reporting, to demonstrate compliance with statutory requirements. Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in part 820 renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

*Change Request –*

To change the regulatory classification of a device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use. In the Federal Register of February 21, 2020 (85 FR 10110), we published a proposed order to reclassify certain devices from class III (premarket approval) into class II (special controls). The devices that are the subject of the reclassification are assigned the generic names "*human immunodeficiency virus (HIV) serological diagnostic and supplemental tests*" and "*human immunodeficiency virus (HIV ) nucleic acid (NAT) diagnostic and supplemental tests that will be reclassified from class III to class II.*" HIV serological diagnostic and supplemental tests are identified as prescription devices for the qualitative detection of HIV antigen(s) and/or detection of antibodies against HIV in human body fluids or tissues; HIV NAT diagnostic and supplemental tests are identified as prescription devices for the qualitative detection of HIV nucleic acid in human body fluids or tissues. Both the HIV serological diagnostic and supplemental tests, and the HIV NAT test diagnostic and supplemental tests, are intended for use as an aid in the diagnosis of infection with HIV, and their results are intended to be interpreted in conjunction with other relevant clinical and laboratory findings. Currently, manufacturers of these devices are subject to the requirements in 21 CFR part 820 and must establish and retain records pertaining to complaint files. While certain complaints that represent reportable adverse

events are subject to reporting under related regulations found in 21 CFR part 803 (medical device reporting; currently approved under OMB control no. 0910-0437), other complaints may represent events that are not subject to the medical device reporting requirements.

We are adding classification regulations for these devices in 21 CFR 866 (Microbiology and Immunology Devices) at 21 CFR 866.3956 for the HIV serological diagnostic and supplemental tests, and 21 CFR 866.3957 for the HIV NAT diagnostic and supplemental tests, and establishing special controls necessary to provide reasonable assurance of their safety and effectiveness. The special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for one of these devices. Manufacturers currently are required to maintain complaint files and to review and evaluate complaints for these devices under 21 CFR 820.198. The special controls would also provide examples of the types of complaints to be included in the log. We intend to review the information in the complaint logs promptly and engage with manufacturers as may be necessary. Complaints required to be reported in these logs, such as unusually high invalid rates or issues with users conducting the test, may not meet the definition of a medical device report under 21 CFR part 803, but could potentially affect the safety and efficacy of these devices. The submission of the complaint log would provide us with earlier notification of concerns and enable us to determine whether issues have been adequately addressed. Although FDA reviews complaint information during routine inspections, the frequency of inspections typically occur less than annually. We believe implementing specific reporting measures as part of the special controls is necessary in providing a reasonable assurance of safety and effectiveness for these devices.

*Burden Adjustment –*

Because respondents to the information collection are already required to retain the information FDA is requesting under 21 CFR 820.198, we have made no adjustment in our burden estimate. Respondents may submit the information electronically through the FDA Electronic Submission Gateway or on paper or electronic media (CD, DVD) to CBER's Document Control Center.

**Submitted: February 2021**