

UNITED STATES FOOD & DRUG ADMINISTRATION
Biological License Applications; Procedures and Requirements
OMB Control Nos. 0910-0338 and 0910-0206

Request for Non-substantive Change:

Information collection activities currently included in OMB control no. 0910-0338 support the implementation of statutory and regulatory requirements that govern biologics product licensing. FDA regulations in 21 CFR parts 600-680 set forth applicable standards and procedures that include associated reporting, recordkeeping, and disclosure requirements. Respondents to the information collection are persons or entities who engage in the manufacture of biologics products. For efficiency of agency operations, we are requesting to add the information collection elements now approved in 0910-0206 to the scope of activity in this collection of information, and account for the attendant burden accordingly. Relatedly, we are requesting to discontinue OMB control no. 0910-0206 upon approval of the modification to 0910-0338. Specifically, we have added a new IC element entitled, “*Requests for samples and protocols*” that cumulatively accounts for the submission of protocols with each sample, as prescribed in the respective regulations, and currently approved in 0910-0206:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
610.2 Requests for samples and protocols; official release	72	82.972	5,974	3	17,922
660.6 Antibody to Hepatitis B surface antigen	3	4	12	5	60
660.36 Reagent red blood cells	1	1	1	6	6
660.46 Hepatitis B surface antigen	1	1	1	5	5
TOTAL	77		5,988		17,993

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers subject to those regulations, respectively. Although no submissions were received under §§ 660.36 or 660.46; we retain a placeholder to account for any future submissions and assume higher-end estimates of 6 and 5 hours, respectively, for the associated activity.

Submitted: September 2024