

written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

“(c) **T IMINGFOR SUBMISSIONFOR REVIEW.**—If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is directed by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

“(d) **T IMINGFOR REVIEWAND CLEARANCE.**—The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

“(e) **N ON-TIMELY REVIEW.**—If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

“(f) **E FFECT.**—Nothing in this section shall be construed as affecting any restrictions on such publication or presentation provided by other provisions of law.”.

SEC. 1102. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

21 USC 360n.

“SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

“(a) **D EFINITIONS.**—In this section:

“(1) **P RIORITYREVIEW .**—The term ‘priority review’, with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

“(2) **P RIORITYREVIEWVOUCHER .**—The term ‘priority review voucher’ means a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351 of the Public Health Service Act after the date of approval of the tropical disease product application.

“(3) **T ROPICALDISEASE .**—The term ‘tropical disease’ means any of the following:

“(A) Tuberculosis.

“(B) Malaria.

“(C) Blinding trachoma.

- “(D) Buruli Ulcer.
- “(E) Cholera.
- “(F) Dengue/dengue haemorrhagic fever.
- “(G) Dracunculiasis (guinea-worm disease).
- “(H) Fascioliasis.
- “(I) Human African trypanosomiasis.
- “(J) Leishmaniasis.
- “(K) Leprosy.
- “(L) Lymphatic filariasis.
- “(M) Onchocerciasis.
- “(N) Schistosomiasis.
- “(O) Soil transmitted helminthiasis.
- “(P) Yaws.

“(Q) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary.

“(4) TROPICAL DISEASE PRODUCT APPLICATION.—The term ‘tropical disease product application’ means an application that—

“(A) is a human drug application as defined in section 735(1)—

“(i) for prevention or treatment of a tropical disease; and

“(ii) the Secretary deems eligible for priority review;

“(B) is approved after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, by the Secretary for use in the prevention, detection, or treatment of a tropical disease; and

“(C) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351 of the Public Health Service Act.

“(b) PRIORITY REVIEW VOUCHER.—

“(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such tropical disease product application.

“(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351 of the Public Health Service Act will be submitted after the date of the approval of the tropical disease product application.

“(3) LIMITATION.—

“(A) NO AWARD FOR PRIOR APPROVED APPLICATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product application was submitted to the Secretary prior to the date of the enactment of this section.

“(B) ONE-YEAR WAITING PERIOD.—The Secretary shall issue a priority review voucher to the sponsor of a tropical disease product no earlier than the date that is 1 year

Deadline.

after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

“(4) NOTIFICATION.—The sponsor of a human drug application shall notify the Secretary not later than 365 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

“(c) PRIORITY REVIEW USER FEE.—

“(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

“(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

“(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

“(4) PAYMENT.—

“(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351 of the Public Health Services Act for which the priority review voucher is used.

“(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary’s procedures for paying such fees.

“(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

“(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

“(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

“(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.”.

SEC. 1103. IMPROVING GENETIC TEST SAFETY AND QUALITY.

Contracts.
Study.

(a) REPORT.—If the Secretary’s Advisory Committee on Genetics, Health, and Society does not complete and submit the Regulatory Oversight of Genetic/Genomic Testing Report & Action Recommendations to the Secretary of Health and Human Services (referred to in this section as the “Secretary”) by July of 2008, the Secretary shall enter into a contract with the Institute of