dition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

(June 25, 1938, ch. 675, § 906, as added Pub. L. 105–115, title II, § 214, Nov. 21, 1997, 111 Stat. 2348.)

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 397. Contracts for expert review

(a) In general

(1) Authority

The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this chapter for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 379 of this title relating to the confidentiality of information.

(2) Increased efficiency and expertise through contracts

The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

(b) Review of expert review

(1) In general

Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) of this section shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

(2) Limitation

A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this chapter or in the Public Health Service Act (42 U.S.C. 201 et seq.).

(June 25, 1938, ch. 675, § 907, as added Pub. L. 105–115, title IV, § 415, Nov. 21, 1997, 111 Stat. 2377.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b)(2), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

CHAPTER 10—POULTRY AND POULTRY PRODUCTS INSPECTION

Sec.