TITLE 21 - FOOD AND DRUGS
CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER V - DRUGS AND DEVICES
Part A - Drugs and Devices

§ 353b. Prereview of television advertisements

(a) In general

The Secretary may require the submission of any television advertisement for a drug (including any
script, story board, rough, or a completed video production of the television advertisement) to the
Secretary for review under this section not later than 45 days before dissemination of the television
advertisement.

(b) Review

In conducting a review of a television advertisement under this section, the Secretary may make
recommendations with respect to information included in the label of the drug—

(1) on changes that are—
   (A) necessary to protect the consumer good and well-being; or
   (B) consistent with prescribing information for the product under review; and

(2) if appropriate and if information exists, on statements for inclusion in the advertisement to
address the specific efficacy of the drug as it relates to specific population groups, including elderly
populations, children, and racial and ethnic minorities.

(c) No authority to require changes

Except as provided by subsection (e), this section does not authorize the Secretary to make or direct
changes in any material submitted pursuant to subsection (a).

(d) Elderly populations, children, racially and ethnically diverse communities

In formulating recommendations under subsection (b), the Secretary shall take into consideration the
impact of the advertised drug on elderly populations, children, and racially and ethnically diverse
communities.

(e) Specific disclosures

(1) Serious risk; safety protocol

In conducting a review of a television advertisement under this section, if the Secretary determines
that the advertisement would be false or misleading without a specific disclosure about a serious
risk listed in the labeling of the drug involved, the Secretary may require inclusion of such
disclosure in the advertisement.

(2) Date of approval

In conducting a review of a television advertisement under this section, the Secretary may require
the advertisement to include, for a period not to exceed 2 years from the date of the approval of the
drug under section 355 of this title or section 262 of title 42, a specific disclosure of such date of
approval if the Secretary determines that the advertisement would otherwise be false or misleading.

(f) Rule of construction

Nothing in this section may be construed as having any effect on requirements under section 352 (n)
of this title or on the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of
title 21, Code of Federal Regulations (or successor regulations).

939.)
Effective Date

Section effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as an Effective Date of 2007 Amendment note under section 331 of this title.