

AMENDMENT TO COMMITTEE PRINT OF H.R. 1108**OFFERED BY MR. PALLONE OF NEW JERSEY**

**Page and line numbers refer to committee print dated March
27, 2008**

Page 14, beginning at line 19, strike paragraph (46)
and insert the following:

1 (46) If manufacturers state or imply in commu-
2 nications directed to consumers through the media
3 or through a label, labeling, or advertising, that a to-
4 bacco product is approved or inspected by the Food
5 and Drug Administration or complies with Food and
6 Drug Administration standards, consumers are like-
7 ly to be confused and misled. Depending upon the
8 particular language used and its context, such a
9 statement could result in consumers being misled
10 into believing that the product is endorsed by the
11 Food and Drug Administration for use or in con-
12 sumers being misled about the harmfulness of the
13 product because of such regulation, inspection, ap-
14 proval, or compliance.

Page 16, line 11, after “products” insert “as pro-
vided for in this Act”.

Page 23, line 21, after “any person” insert “, government, or entity”.

Page 24, after line 6, insert the following (and make such conforming amendments as may be necessary):

1 “(15) SMALL TOBACCO PRODUCT MANUFAC-
2 TURER.—The term ‘small tobacco product manufac-
3 turer’ means a tobacco product manufacturer that
4 employs fewer than 350 employees. For purposes of
5 determining the number of employees of a manufac-
6 turer under the preceding sentence, the employees of
7 a manufacturer are deemed to include the employees
8 of each entity that controls, is controlled by, or is
9 under common control with such manufacturer.

Page 25, after line 4, insert the following (and make such technical and conforming changes as may be necessary):

10 “(19) TOBACCO WAREHOUSE.—
11 “(A) Subject to subparagraphs (B) and
12 (C), the term ‘tobacco warehouse’ includes any
13 person—
14 “(i) who—
15 “(I) removes foreign material
16 from tobacco leaf through nothing
17 other than a mechanical process;

1 “(II) humidifies tobacco leaf with
2 nothing other than potable water in
3 the form of steam or mist; or

4 “(III) de-stems, dries, and packs
5 tobacco leaf for storage and shipment;

6 “(ii) who performs no other actions
7 with respect to tobacco leaf; and

8 “(iii) who provides to any manufac-
9 turer to whom the person sells tobacco all
10 information related to the person’s actions
11 described in clause (i) that is necessary for
12 compliance with this Act.

13 “(B) The term ‘tobacco warehouse’ ex-
14 cludes any person who—

15 “(i) reconstitutes tobacco leaf;

16 “(ii) is a manufacturer, distributor, or
17 retailer of a tobacco product; or

18 “(iii) applies any chemical, additive,
19 or substance to the tobacco leaf other than
20 potable water in the form of steam or mist.

21 “(C) The definition of the term ‘tobacco
22 warehouse’ in subparagraph (A) shall not apply
23 to the extent to which the Secretary determines,
24 through rulemaking, that regulation under this
25 chapter of the actions described in such sub-

1 paragraph is appropriate for the protection of
2 the public health.

Page 28, after line 8, insert the following:

3 “(g) CONSULTATION PRIOR TO RULEMAKING.—Prior
4 to promulgating rules under this chapter, the Secretary
5 shall endeavor to consult with other Federal agencies as
6 appropriate.

Page 40, line 7, strike “OF” and insert “BY”.

Page 41, lines 18 and 19, strike “FOREIGN ESTAB-
LISHMENTS SHALL REGISTER” and insert “REGISTRA-
TION BY FOREIGN ESTABLISHMENTS”.

Page 52, after line 17, insert the following:

7 “(4) REMOTE SALES.—
8 “(A) IN GENERAL.—The Secretary shall—
9 “(i) within 18 months after the date
10 of enactment of this chapter, promulgate
11 regulations regarding the sale and distribu-
12 tion of tobacco products that occur
13 through means other than a direct, face-to-
14 face exchange between a retailer and a
15 consumer in order to prevent the sale and
16 distribution of tobacco products to individ-
17 uals who have not attained the minimum

1 age established by applicable law for the
2 purchase of such products, including re-
3 quirements for age verification; and

4 “(ii) within 2 years after such date of
5 enactment, issue regulations to address the
6 promotion and marketing of tobacco prod-
7 ucts that are sold or distributed through
8 means other than a direct, face-to-face ex-
9 change between a retailer and a consumer
10 in order to protect individuals who have
11 not attained the minimum age established
12 by applicable law for the purchase of such
13 products.

14 “(B) RELATION TO OTHER AUTHORITY.—
15 Nothing in this paragraph limits the authority
16 of the Secretary to take additional actions
17 under the other paragraphs of this subsection.

Page 52, line 22, through page 53, line 13, amend
subparagraph (A) to read as follows:

18 “(A) IN GENERAL.—In applying manufac-
19 turing restrictions to tobacco, the Secretary
20 shall, in accordance with subparagraph (B),
21 prescribe regulations (which may differ based
22 on the type of tobacco product involved) requir-
23 ing that the methods used in, and the facilities

1 and controls used for, the manufacture,
2 preproduction design validation (including a
3 process to assess the performance of a tobacco
4 product), packing, and storage of a tobacco
5 product conform to current good manufacturing
6 practice, or hazard analysis and critical control
7 point methodology, as prescribed in such regu-
8 lations to assure that the public health is pro-
9 tected and that the tobacco product is in com-
10 pliance with this chapter. Such regulations may
11 provide for the testing of raw tobacco for pes-
12 ticide chemical residues regardless of whether a
13 tolerance for such chemical residues has been
14 established.

Page 54, after line 17, insert the following (and
make such conforming changes as may be necessary):

15 “(v) not require any small tobacco
16 product manufacturer to comply with a
17 regulation under subparagraph (A) for at
18 least 4 years following the effective date
19 established by the Secretary for such regu-
20 lation.”.

Page 57, lines 19 through 25, strike “before the pe-
riod ending” and all that follows through “3 years after

such date of enactment” and insert “before the end of the 3-year period following the date of enactment of the Family Smoking Prevention and Tobacco Control Act”.

Page 58, line 10, strike “SPECIAL RULE FOR CIGARETTES” and insert “SPECIAL RULES”.

Page 58, beginning at line 10, strike “Beginning” and insert the following:

1 “(A) SPECIAL RULE FOR CIGARETTES.—
2 Beginning

Page 59, line 2, after “this paragraph.” insert “For purposes of this section, a cigarette or any of its component parts has a characterizing flavor if the cigarette, its tobacco smoke, or the component part imparts a distinguishable taste or aroma other than tobacco or menthol either prior to consumption or during consumption, or is advertised or marketed as having or producing a flavor, taste, or aroma other than tobacco or menthol.”.

Page 59, after line 2, insert the following:

3 “(B) ADDITIONAL SPECIAL RULE.—No to-
4 bacco product manufactured in or imported into
5 the United States shall contain foreign-grown
6 tobacco that—

1 “(i) contains a level of any pesticide,
2 insecticide, herbicide, or fungicide in excess
3 of any maximum permissible residue level
4 that is applicable to domestically grown to-
5 bacco; or
6 “(ii) was grown or processed using
7 any pesticide, insecticide, herbicide, or fun-
8 gicide that the Environmental Protection
9 Agency has not approved for use in domes-
10 tic tobacco farming or processing.

Page 59, strike lines 14 through 23 and insert the following:

11 “(i) CONSIDERATIONS.—In making a
12 finding described in subparagraph (A), the
13 Secretary shall consider scientific evidence
14 concerning—
15 “(I) the risks and benefits to the
16 population as a whole, including users
17 and nonusers of tobacco products, of
18 the proposed standard;

Page 60, strike lines 7 through 16 and insert the following:

19 “(ii) ADDITIONAL CONSIDER-
20 ATIONS.—In the event that the Secretary

1 makes a determination, set forth in a pro-
2 posed tobacco product standard in a pro-
3 posed rule, that it is appropriate for the
4 protection of public health to require the
5 reduction or elimination of an additive,
6 constituent (including a smoke con-
7 stituent), or other component of a tobacco
8 product because the Secretary has found
9 that the additive, constituent, or other
10 component is or may be harmful, any
11 party objecting to the proposed standard
12 on the ground that the proposed standard
13 will not reduce or eliminate the risk of ill-
14 ness or injury may provide for the Sec-
15 retary's consideration scientific evidence
16 that demonstrates that the proposed stand-
17 ard will not reduce or eliminate the risk of
18 illness or injury.

Page 62, after line 9, insert the following (and make
such conforming changes as may be necessary):

19 “(D) shall require tobacco products con-
20 taining foreign-grown tobacco to meet the same
21 standards applicable to tobacco products con-
22 taining domestically grown tobacco.

Page 63, after line 9, insert the following:

1 “(b) CONSIDERATIONS BY SECRETARY.—

2 “(1) TECHNICAL ACHIEVABILITY.—The Sec-
3 retary shall consider information submitted in con-
4 nection with a proposed standard regarding the tech-
5 nical achievability of compliance with such standard.

6 “(2) OTHER CONSIDERATIONS.—The Secretary
7 shall consider all other information submitted in
8 connection with a proposed standard, including in-
9 formation concerning the countervailing effects of
10 the tobacco product standard on the health of ado-
11 lescent tobacco users, adult tobacco users, or non-
12 tobacco users, such as the creation of a significant
13 demand for contraband or other tobacco products
14 that do not meet the requirements of this chapter
15 and the significance of such demand.

Page 63, line 10, redesignate subsection (b) as sub-
section (c) (and make such conforming changes as may
be necessary).

Page 63, line 10, strike “ESTABLISHMENT OF
STANDARDS” and insert “PROPOSED STANDARDS”

Page 64, strike lines 1 through 5, strike clause (ii)
and redesignate clause (iii) as clause (ii).

Page 64, after line 8, insert the following:

1 “(iii) invite interested persons to sub-
2 mit comments on structuring the standard
3 so that it does not advantage foreign-
4 grown tobacco over domestically grown to-
5 bacco; and
6 “(iv) invite the Secretary of Agri-
7 culture to provide any information or anal-
8 ysis which the Secretary of Agriculture be-
9 lieves is relevant to the proposed tobacco
10 product standard.

Page 64, strike line 15 and all that follows through page 65, line 3.

Page 65, line 4, redesignate subparagraph (E) as subparagraph (D).

Page 65, line 7, redesignate paragraph (2) as subsection (d) (and make such conforming changes as may be necessary).

Page 65, line 12, after “such comments” insert “submitted under subsections (b) and (c)”.

Page 65, line 14, after “Committee,” insert “if the Secretary determines that the standard would be appropriate for the protection of the public health,”.

Page 66, line 10, after “international trade.” insert the following: “In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary’s evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.”.

Page 92, line 19, strike “or ‘does not produce smoke’.” and insert “‘does not produce smoke’, ‘smokefree’, ‘smoke-free’, ‘without smoke’, ‘no smoke’, or ‘not smoke’.”.

Page 106, after line 23, insert the following (and make such conforming changes as may be necessary):

1 “(F) establish a reasonable timetable for
2 the Secretary to review an application under
3 this section.

Page 112, lines 12 through 19, amend the text of section 915 of the Federal Food, Drug, and Cosmetic Act, as added by the committee print, to read “Section 801 of title 5, United States Code, shall not apply to the final rule published under paragraph (1).” and transfer such section 915 so that it appears as a new paragraph at the end of section 102(a) of the committee print (and make such conforming changes as may be necessary).

Page 112, beginning at line 24, strike “, acting through the Commissioner of Food and Drugs,”.

Page 113, lines 21 and 22, strike “The Commissioner of Food and Drugs” and insert “The Secretary”.

Page 113, after line 25, at the end of section 916 add the following:

4 “(d) SMALL TOBACCO PRODUCT MANUFACTUR-
5 ERS.—

6 “(1) FIRST COMPLIANCE DATE.—The initial
7 regulations promulgated under subsection (a) shall
8 not impose requirements on small tobacco product
9 manufacturers before the later of—

1 “(A) the end of the 2-year period following
2 the final promulgation of such regulations; and

3 “(B) the initial date set by the Secretary
4 for compliance with such regulations by manu-
5 facturers that are not small tobacco product
6 manufacturers.

7 “(2) TESTING AND REPORTING INITIAL COM-
8 PLIANCE PERIOD.—

9 “(A) 4-YEAR PERIOD.—The initial regula-
10 tions promulgated under subsection (a) shall
11 give each small tobacco product manufacturer a
12 4-year period over which to conduct testing and
13 reporting for all of its tobacco products. Subject
14 to paragraph (1), the end of the first year of
15 such 4-year period shall coincide with the initial
16 date of compliance under this section set by the
17 Secretary with respect to manufacturers that
18 are not small tobacco product manufacturers or
19 the end of the 2-year period following the final
20 promulgation of such regulations, as described
21 in paragraph (1)(A). A small tobacco product
22 manufacturer shall be required—

23 “(i) to conduct such testing and re-
24 porting for 25 percent of its tobacco prod-

1 ucts during each year of such 4-year pe-
2 riod; and

3 “(ii) to conduct such testing and re-
4 porting for its largest-selling tobacco prod-
5 ucts (as determined by the Secretary) be-
6 fore its other tobacco products, or in such
7 other order of priority as determined by
8 the Secretary.

9 “(B) CASE-BY-CASE DELAY.—Notwith-
10 standing subparagraph (A), the Secretary may,
11 on a case-by-case basis, delay the date by which
12 an individual small tobacco product manufac-
13 turer must conduct testing and reporting for its
14 tobacco products under this section based upon
15 a showing of undue hardship to such manufac-
16 turer. Notwithstanding the preceding sentence,
17 the Secretary shall not extend the deadline for
18 a small tobacco product manufacturer to con-
19 duct testing and reporting for all of its tobacco
20 products beyond a total of 5 years after the ini-
21 tial date of compliance under this section set by
22 the Secretary with respect to manufacturers
23 that are not small tobacco product manufactur-
24 ers.

1 “(3) SUBSEQUENT AND ADDITIONAL TESTING
2 AND REPORTING.—The regulations promulgated
3 under subsection (a) shall provide that, with respect
4 to any subsequent or additional testing and report-
5 ing of tobacco products required under this section,
6 such testing and reporting by a small tobacco prod-
7 uct manufacturer shall be conducted in accordance
8 with the timeframes described in paragraph (2)(A),
9 except that, in the case of a new product, or if there
10 has been a modification described in section
11 910(a)(1)(B) of any product of a small tobacco
12 product manufacturer since the last testing and re-
13 porting required under this section, the Secretary
14 shall require that any subsequent or additional test-
15 ing and reporting be conducted in accordance with
16 the same timeframe applicable to manufacturers
17 that are not small tobacco product manufacturers.

18 “(4) JOINT LABORATORY TESTING SERVICES.—
19 The Secretary shall allow any 2 or more small to-
20 bacco product manufacturers to join together to pur-
21 chase laboratory testing services required by this
22 section on a group basis in order to ensure that such
23 manufacturers receive access to, and fair pricing of,
24 such testing services.

1 “(e) EXTENSIONS FOR LIMITED LABORATORY CA-
2 PACITY.—

3 “(1) IN GENERAL.—The regulations promul-
4 gated under subsection (a) shall provide that a small
5 tobacco product manufacturer shall not be consid-
6 ered to be in violation of this section before the
7 deadline applicable under paragraphs (3) and (4),
8 if—

9 “(A) the tobacco products of such manu-
10 facturer are in compliance with all other re-
11 quirements of this chapter; and

12 “(B) the conditions described in paragraph
13 (2) are met.

14 “(2) CONDITIONS.—Notwithstanding the re-
15 quirements of this section, the Secretary may delay
16 the date by which a small tobacco product manufac-
17 turer must be in compliance with the testing and re-
18 porting required by this section until such time as
19 the testing is reported if, not later than 90 days be-
20 fore the deadline for reporting in accordance with
21 this section, a small tobacco product manufacturer
22 provides evidence to the Secretary demonstrating
23 that—

24 “(A) the manufacturer has submitted the
25 required products for testing to a laboratory

1 and has done so sufficiently in advance of the
2 deadline to create a reasonable expectation of
3 completion by the deadline;

4 “(B) the products currently are awaiting
5 testing by the laboratory; and

6 “(C) neither that laboratory nor any other
7 laboratory is able to complete testing by the
8 deadline at customary, nonexpedited testing
9 fees.

10 “(3) EXTENSION.—The Secretary, taking into
11 account the laboratory testing capacity that is avail-
12 able to tobacco product manufacturers, shall review
13 and verify the evidence submitted by a small tobacco
14 product manufacturer in accordance with paragraph
15 (2). If the Secretary finds that the conditions de-
16 scribed in such paragraph are met, the Secretary
17 shall notify the small tobacco product manufacturer
18 that the manufacturer shall not be considered to be
19 in violation of the testing and reporting require-
20 ments of this section until the testing is reported or
21 until 1 year after the reporting deadline has passed,
22 whichever occurs sooner. If, however, the Secretary
23 has not made a finding before the reporting dead-
24 line, the manufacturer shall not be considered to be
25 in violation of such requirements until the Secretary

1 finds that the conditions described in paragraph (2)
2 have not been met, or until 1 year after the report-
3 ing deadline, whichever occurs sooner.

4 “(4) **ADDITIONAL EXTENSION.**—In addition to
5 the time that may be provided under paragraph (3),
6 the Secretary may provide further extensions of
7 time, in increments of no more than 1 year, for re-
8 quired testing and reporting to occur if the Sec-
9 retary determines, based on evidence properly and
10 timely submitted by a small tobacco product manu-
11 facturer in accordance with paragraph (2), that a
12 lack of available laboratory capacity prevents the
13 manufacturer from completing the required testing
14 during the period described in paragraph (3).

15 “(f) **RULE OF CONSTRUCTION.**—Nothing in sub-
16 section (d) or (e) shall be construed to authorize the exten-
17 sion of any deadline, or to otherwise affect any timeframe,
18 under any provision of this Act or the Family Smoking
19 Prevention and Tobacco Control Act other than this sec-
20 tion.

Strike page 122, line 10, through page 125, line 25,
and insert the following:

21 **“SEC. 920. USER FEE.**

22 “(a) **ESTABLISHMENT OF QUARTERLY USER FEE.**—
23 The Secretary shall assess a quarterly user fee with re-

1 spect to every quarter of each fiscal year commencing fis-
2 cal year 2008, calculated in accordance with this section,
3 upon each manufacturer and importer of tobacco products
4 subject to this chapter.

5 “(b) FUNDING OF FDA REGULATION OF TOBACCO
6 PRODUCTS.—

7 “(1) IN GENERAL.—The Secretary shall make
8 user fees collected pursuant to subsection (c)(1)
9 available to pay, in each fiscal year beginning with
10 fiscal year 2008, for the costs of the activities of the
11 Food and Drug Administration related to the regu-
12 lation of tobacco products under this chapter and
13 the Family Smoking Prevention and Tobacco Con-
14 trol Act. No fees collected pursuant to subsection
15 (c)(1) may be used by the Secretary for any other
16 costs.

17 “(2) AVAILABILITY.—Subject to paragraph (1),
18 fees collected pursuant to subsection (c)(1) shall be
19 available to the Secretary without further appropria-
20 tion in the following amounts:

21 “(A) For fiscal year 2008, \$85,000,000.

22 “(B) For fiscal year 2009, \$235,000,000.

23 “(C) For fiscal year 2010, \$450,000,000.

24 “(D) For fiscal year 2011, \$477,000,000.

25 “(E) For fiscal year 2012, \$505,000,000.

1 “(F) For fiscal year 2013, \$534,000,000.

2 “(G) For fiscal year 2014, \$566,000,000.

3 “(H) For fiscal year 2015, \$599,000,000.

4 “(I) For fiscal year 2016, \$635,000,000.

5 “(J) For fiscal year 2017, \$672,000,000.

6 “(K) For fiscal year 2018 and each subse-
7 quent fiscal year, \$712,000,000.

8 Fees made available to the Secretary under this
9 paragraph shall remain available until expended.

10 “(3) OFFSETTING RECEIPTS.—Fees collected
11 pursuant to subsection (c)(1) shall be recorded as
12 offsetting receipts.

13 “(4) PROHIBITION AGAINST USE OF OTHER
14 FUNDS.—

15 “(A) IN GENERAL.—Except as provided in
16 subparagraph (B), fees collected pursuant to
17 this section shall be the only funds used to pay
18 the costs of the activities of the Food and Drug
19 Administration related to the regulation of to-
20 bacco products under this chapter and the
21 Family Smoking Prevention and Tobacco Con-
22 trol Act.

23 “(B) STARTUP COSTS.—Subparagraph (A)
24 shall not apply until the date on which the Sec-
25 retary has collected fees pursuant to this sec-

1 tion for 2 fiscal year quarters. Until such date,
2 amounts available to the Food and Drug Ad-
3 ministration (other than fees collected pursuant
4 to this section) may be used to pay the costs
5 described in subparagraph (A), provided that
6 such amounts are reimbursed through such
7 fees.

8 “(c) ASSESSMENT OF USER FEE.—

9 “(1) AMOUNT OF ASSESSMENT.—The assess-
10 ment under this section for—

11 “(A) fiscal year 2008 shall be
12 \$90,100,000;

13 “(B) fiscal year 2009 shall be
14 \$249,100,000;

15 “(C) fiscal year 2010 shall be
16 \$477,000,000;

17 “(D) fiscal year 2011 shall be
18 \$505,620,000;

19 “(E) fiscal year 2012 shall be
20 \$535,300,000;

21 “(F) fiscal year 2013 shall be
22 \$566,040,000;

23 “(G) fiscal year 2014 shall be
24 \$599,960,000;

1 “(H) fiscal year 2015 shall be
2 \$634,940,000;
3 “(I) fiscal year 2016 shall be
4 \$673,100,000;
5 “(J) fiscal year 2017 shall be
6 \$712,320,000; and
7 “(K) fiscal year 2018 and each subsequent
8 fiscal year shall be \$754,720,000.

Page 127, beginning on line 1, strike “determined” and all that follows through “such class” on line 4 and insert the following: “determined under section 625(c) of Public Law 108-357 for each such class”.

Page 127, lines 20 and 21, strike “on a pro rata basis”.

Page 127, line 22, after “chapter” insert “in the same manner and based on the same relative percentages otherwise determined under clause (ii)”.

Page 128, beginning on line 24, strike “determined” and all that follows through page 129, line 2, and insert the following: “determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108-357.”.

Page 129, strike line 19 and all that follows through page 130, line 5, and insert the following:

1 “(1) IN GENERAL.—The Secretary shall request
2 the appropriate Federal agency to enter into a
3 memorandum of understanding that provides for the
4 regular and timely transfer from the head of such
5 agency to the Secretary of the information described
6 in paragraphs (2)(B)(ii) and (4) of subsection (c)
7 and all necessary information regarding all tobacco
8 product manufacturers and importers required to
9 pay user fees. The Secretary shall maintain all dis-
10 closure restrictions established by the head of such
11 agency regarding the information provided under the
12 memorandum of understanding.

Page 130, beginning on line 13, strike “a contract”
and all that follows through “to continue” on line 14 and
insert the following: “a contract with the head of the
Federal agency referred to in paragraph (1) to continue”.

Page 130, after line 25, insert the following:

13 “(g) STUDY BY GAO.—
14 “(1) IN GENERAL.—The Comptroller General of
15 the United States shall conduct a study on—
16 “(A) the prevalence of youth tobacco use
17 and the brands and subbrands that individuals
18 under the age of 18 consume;

1 “(B) the feasibility of structuring the user
2 fees or a portion of the user fees collected under
3 this section on the youth market share of a
4 manufacturer or year to year changes in a man-
5 ufacturer’s share of youth market; and

6 “(C) the potential effects of tobacco mar-
7 keting to youth audiences if user fees were cal-
8 culated in whole or in part on youth market
9 share.

10 “(2) REPORT.—The Comptroller General shall
11 submit to the Energy and Commerce Committee of
12 the House of Representatives and the Health, Edu-
13 cation, Labor, and Pension Committee of the Senate
14 a report on the study conducted under paragraph
15 (1) by not later than 3 years after the date of enact-
16 ment of the Family Smoking Prevention and To-
17 bacco Control Act.”.

Page 131, lines 3 and 4, strike “Not later than 30 days after the date of enactment of this Act” and insert “On the first day of publication of the Federal Register that is 180 days or more after the date of enactment of this Act”.

Page 131, lines 11 through 13, strike subparagraph (B) and insert the following:

1 (B) shall be deemed to be in compliance
2 with all applicable provisions of chapter 5 of
3 title 5, United States Code, and all other provi-
4 sions of law relating to rulemaking procedures.

On page 132, line 9, strike, “not later than” and in-
sert “on the date that is”.

Page 135, after line 23, insert the following (and
make such conforming changes as may be necessary):

5 “(5) Nothing in this paragraph shall be construed to
6 authorize any person to distribute or cause to be distrib-
7 uted any sample of a tobacco product to any individual
8 who has not attained the minimum age established by ap-
9 plicable law for the purchase of such product.”.

Page 136, after line 11, insert the following:

10 (5) ENFORCEMENT OF RETAIL SALE PROVI-
11 SIONS.—The Secretary of Health and Human Serv-
12 ices shall ensure that the provisions of this Act, the
13 amendments made by this Act, and the imple-
14 menting regulations (including such provisions,
15 amendments, and regulations relating to the retail
16 sale of tobacco products) are enforced with respect
17 to the United States and Indian tribes.

18 (6) QUALIFIED ADULT-ONLY FACILITY.—A
19 qualified adult-only facility (as such term is defined

1 in section 897.16(d) of the final rule published
2 under paragraph (1)) that is also a retailer and that
3 commits a violation as a retailer shall not be subject
4 to the limitations in section 103(q) and shall be sub-
5 ject to penalties applicable to a qualified adult-only
6 facility.

Page 148, line 20, strike “the retailer’s address of record or” and insert “the location specified on the retailer’s registration or to”.

Page 150, after line 9, insert the following (and make such conforming changes as may be necessary):

7 (G) providing for the Secretary, in deter-
8 mining whether to impose a no-tobacco-sale
9 order and in determining whether to com-
10 promise, modify, or terminate such an order, to
11 consider whether the retailer has taken effective
12 steps to prevent violations of the minimum age
13 requirements for the sale of tobacco products,
14 including the steps listed in subparagraph (F).

Page 151, line 8, after “violation” insert “within a 48-month period”.

Page 152, line 5, after “violation” insert “within a 48-month period”.

Page 152, after line 12, insert the following:

1 (C) CONSIDERATION OF STATE PEN-
2 ALTIES.—The Secretary shall coordinate with
3 the States in enforcing the provisions of this
4 Act and, for purposes of mitigating a civil pen-
5 alty to be applied for a violation by a retailer
6 of any restriction promulgated under section
7 906(d), shall consider the amount of any pen-
8 alties paid by the retailer to a State for the
9 same violation.

Page 153, after line 13, insert the following:

10 **SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PUR-**
11 **CHASE TOBACCO PRODUCTS.**

12 The Secretary of Health and Human Services shall—
13 (1) convene an expert panel to conduct a study
14 on the public health implications of raising the min-
15 imum age to purchase tobacco products; and
16 (2) not later than 5 years after the date of the
17 enactment of this Act, submit a report to the Con-
18 gress on the results of such study.

Page 156, line 1, before “tobacco product manufac-
turer” insert “license- or permit-holding”.

Page 160, lines 17 and 18, strike “is not labeled in
accordance with the requirements of subsection (b)” and

insert “does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b)”.

Page 164, lines 9 through 14, strike “that is supplied” and all that follows through “in accordance with this subsection.” and insert the following: “that—”

1 “(A) contains a warning label;
2 “(B) is supplied to the retailer by a
3 license- or permit-holding tobacco product man-
4 ufacturer, importer, or distributor; and
5 “(C) is not altered by the retailer in a way
6 that is material to the requirements of this sub-
7 section.

Page 166, lines 22 and 23, strike “is not labeled in accordance with the requirements of this subsection” and insert “does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection”.

Page 166, after line 23, insert the following:

8 “(5) ADJUSTMENT BY SECRETARY.—The Sec-
9 retary may, through a rulemaking under section 553
10 of title 5, United States Code, adjust the format and
11 type sizes for the label statements required by this
12 section; the text, format, and type sizes of any re-

1 quired tar, nicotine yield, or other constituent dislo-
2 sures; or the text, format, and type sizes for any
3 other disclosures required under the Federal Food,
4 Drug, and Cosmetic Act. The text of any such label
5 statements or disclosures shall be required to appear
6 only within the 20 percent area of advertisements
7 provided by paragraph (2). The Secretary shall pro-
8 mulgate regulations which provide for adjustments
9 in the format and type sizes of any text required to
10 appear in such area to ensure that the total text re-
11 quired to appear by law will fit within such area.