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(Original Signature of Member)

110TH CONGRESS
1ST SESSION

H. R. l l

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

IN THE HOUSE OF REPRESENTATIVES

Mr. WAXMAN introduced the following bill; which was referred to the Committee on l l l l l l l l l l l l l l

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A BILL

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Family Smoking Prevention and Tobacco Control Act''.

(b) TABLE OF CONTENTS.—The table of contents of

SEC. 2. FINDINGS.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in

(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs.

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

(16) In 2003, the cigarette manufacturers spent more than $15,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

(18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons

under the age of 18 are regularly exposed to tobacco product promotional efforts.

(19) Through advertisements during and spon-

while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion plays a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to

vey information about their products to adult consumers.

(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thou

smoking entirely and thereby lead to disease and death.

(39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from ''low tar'' and ''light'' cigarettes and such products may actually increase the risk of tobacco use.

(40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in insuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.

(41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health.

(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be approved in advance of marketing, and to require that the evidence relied on to support approval of these products is rigorous.

SEC. 3. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products;

(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health official 1 Tf-3.71val ofg0 Tf5dj/eq.(spe

other person or circumstance shall not be affected and

which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

''(9) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given such term in section 4(e) of the Indian Self Determination and Education Assistance Act.

''(10) LITTLE CIGAR.—The term 'little cigar' has the meaning given that term by section 3(7) of the Federal Cigarette Labeling and Advertising Act.

''(11) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1–Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

''(12) PACKAGE.—The term 'package' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

''(13) RETAILER.—The term 'retailer' means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

''(14) ROLL-YOUR-OWN TOBACCO.—The term

Mariana Islands, and any other trust territory or

"**SEC. 902. ADULTERATED TOBACCO PRODUCTS.**

''A tobacco product shall be deemed to be adulterated if—

''(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

''(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

''(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

''(4) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

''(5)(A) it is required by section 910(a) to have premarket approval and does not have an approved application in effect; or

''(B) it is in violation of the order approving such an application;

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''(6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if

‘‘(1) A listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

gress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

''(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

''(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.

''(c) REGISTRATION OF NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

''(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufac-

gaged in the manufacture, preparation, compounding, or

paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

''(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

''(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary ks8 1 rr2ll 1430TD0

retary requests such a statement with respect to that particular tobacco product.

''(2) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

''(A) A list of each tobacco product introduced by the registrant for commercial distribu-

tribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of June 1, 2003, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

''(A) the basis for such person's determination that the tobacco product is substantially

"SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

''(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal

such regulation would be appropriate for the protec-

under subsection (a) as the Secretary may in such regulation prescribe.

''(3) LIMITATIONS.—

''(A) IN GENERAL.—No restrictions under paragraph (1) may—

''(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

''(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

''(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not6grkh1 Tf-7.2143 0 Tt s[e 0 1

Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

''(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

''(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

''(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices.

''(2) EXEMPTIONS; VARIANCES.—

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''(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

''(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco

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''(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the period ending 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes without regard to section 3324(a) and (b) of title 31, United States Code, and section 5 of title 41, United States Code.

"**SEC. 907. TOBACCO PRODUCT STANDARDS.**

''(a) IN GENERAL.—

''(1) SPECIAL RULE FOR CIGARETTES.—A ciga-

‘‘(iii) provisions for the measurement

Secretary may provide for testing under paragraph (4)(B) by any person.

''(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

''(A) use personnel, facilities, and other technical support available in other Federal agencies;

''(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and

''(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

''(b) ESTABLISHMENT OF STANDARDS.—

''(1) NOTICE.—

''(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amend-

ment, or revocation of any tobacco product standard.

''(B) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

''(i) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

''(ii) set forth proposed findings with respect 45tt-cn9.7143 -1.8571.0u8rth a5;

the proposed standard to prove that the proposed standard will not reduce or eliminate the risk of illness or injury.

''(F) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

''(2) PROMULGATION.—

''(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed

publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

''(3) POWER RESERVED TO CONGRESS.—Because of the importance of a decision of the Secretary to issue a regulation establishing a tobacco

‘‘(b) NO EXEMPTION FROM OTHER LIABILITY.—

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

''(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a) of this section.

"SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

''(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product

pected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

''(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

''(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

''(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

''(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

''(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

‘‘(B) to remedy a violation of this chapter caused by the tobacco produqMP211s Tm0 g/GS1 gs0 Tc7

stituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after June 1, 2003.

''(2) PREMARKET APPROVAL REQUIRED.—

''(A) NEW PRODUCTS.—Approval under this section of an application for premarket approval for any new tobacco product is required unless—

''(i) the manufacturer has submitted a

regulation issued under section 905(j)(3).

''(B) APPLICATION TO CERTAIN POST JUNE 1, 2003 PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

''(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2003, and prior to the date that is 15 months after the date of enactment of the Family Smok-

the predicate tobacco product, that the Secretary by order has found that the tobacco product—

''(i) has the same characteristics as the predicate tobacco product; or

''(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

''(B) CHARACTERISTICS.—In subparagraph (A), the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

''(C) LIMITATION.—A tobacco product may not be1 Tf-5.239.0001 Tt3dacco product may

er such tobacco product presents less risk than other tobacco products;

''(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

''(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

''(D) an identifying reference to any tobacco product standard under section 907

and recommendation submitted under paragraph (2) of such subsection, shall—

''(i) issue an order approving the application if the Secretary finds that none of

and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

''(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

''(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

''(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

''(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, compliance with which is a condition to approval of the application, and there is a lack of adequate information to justify the deviation from such standard.

''(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement in-

forming the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

''(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether approval of a tobacco product is appropriate for the protection of the public health shall .

clude 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

''(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product the Secretary may authorize that the determination

''(B) that the application contained or was accompanied by an untrue statement of a material fact;

''(C) that the applicant—

''(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

''(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

''(iii) has not complied with the requirements of section 905;

''(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a

reasonable time after receipt of written notice

which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 912.

''(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco

''(1) ADDITIONAL INFORMATION.—In the case

ucts, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

''(B) LIMITATION.—No tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products', except as described in subparagraph (A).

''(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section and is subject to the requirements of chapter V.

''(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—

''(1) a description of the proposed product and any proposed advertising and labeling;

''(2) the conditions for using the product;

''(3) the formulation of the product;

''(4) sample product labels and labeling;

''(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco

product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

''(6) data and information on how consumers actually use the tobacco product; and

''(7) such other information as the Secretary may require.

''(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

''(f) ADVISORY COMMITTEE.—

''(1) IN GENERAL.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this subsection.

''(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee

under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.

''(g) APPROVAL.—

''(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Secretary shall approve an application for a modified risk tobacco product filed under this section only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

''(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

''(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

''(A) IN GENERAL.—The Secretary may approve an application for a tobacco product that has not been approved as a modified risk tobacco product pursuant to paragraph (1) if the Secretary makes the findings required

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under this paragraph and determines that the applicant has demonstrated that—

''(i) the approval of the application would be appropriate to promote the public health;

''(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b)(2) is limited to an explicit or implicit representation that such tobacco product or its smoke contains or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

''(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

''(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in

morbidity or mortality among individual tobacco users is anticipated in subsequent studies.

''(B) ADDITIONAL FINDINGS REQUIRED.—In order to approve an application under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—

''(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

''(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the anticipated overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

''(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

''(I) is or has been demonstrated to be less harmful; or

''(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

''(iv) approval of the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(C) CONDITIONS OF APPROVAL.—

''(i) IN GENERAL.—Applications approved under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

‘‘(ii) AGREEMENTS BY APPLICANT.—Applications approved under this paragraph shall be conditioned on the applicant’s agreement to conduct post-market surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the application approval on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the ap-

determinations under paragraphs (1) and (2), the Secretary shall take into account—

''(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

''(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

''(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

''(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence; and

tion under this section that any advertising or label-

shall be stated in immediate proximity to the most prominent claim.

''(3) LABEL DISCLOSURE.—

''(A) IN GENERAL.—The Secretary may re-

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‘‘(C) any postmarket surveillance or studies reveal that the approval of the application is no longer consistent with the protection of the public health;

‘‘(4) the applicant failed to conduct or submit the postmarket surveillance and studies required

‘‘(3) REVISION.—The regulations or guidance

‘‘(ii) a statement of the reasons for the issuance of such a regulation or order.

‘‘(C) DEFINITION OF RECORD.—In this section, the term ‘record’ means—

lief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

''(c) FINALITY OF JUDGMENT.—The judgment of the

in the advertising of cigarettes or smokeless tobacco; and

''(2) the Secretary shall consult with the Chairman of such Commission in revising the label state-

protect the public health. The regulations may require

products that is in addition to, or more stringent

‘‘(A) MEMBERS.—The Secretary shall ap-

is the applicable percentage of the total costs of activities of the Food and Drug Administration described in subsection (b).

''(B) APPLICABLE PERCENTAGE.—For purposes of subparagraph (A), the applicable percentage for a fiscal year shall be the following:

''(i) 92.07 percent shall be assessed on manufacturers and importers of cigarettes;

''(ii) 0.05 percent shall be assessed on manufacturers and importers of little cigars;

''(iii) 7.15 percent shall be assessed on manufacturers and importers of cigars other than little cigars;

''(iv) 0.43 percent shall be assessed on manufacturers and importers of snuff;

''(v) 0.10 percent shall be assessed on manufacturers and importers of chewing tobacco;

''(vii) 0.14 percent shall be assessed on manufacturers and importers of roll-your-own tobacco.

''(3) DISTRIBUTION OF FEE SHARES OF MANUFACTURERS AND IMPORTERS EXEMPT FROM USER FEE.—Where a class of tobacco products is not subject to a user fee under this section, the portion of the user fee assigned to such class under paragraph (2) shall be allocated by the Secretary on a pro rata basis among the classes of tobacco products that are subject to a user fee under this section. Such pro rata allocation for each class of tobacco products that is subject to a user fee under this section shall be the quotient of—

''(A) the percentage assigned to such class under paragraph (2); divided by

''(B) the sum of the percentages assigned to all classes of tobacco products subject to this section.

''(4) ANNUAL LIMIT ON ASSESSMENT.—The total assessment under this section—

''(A) for fiscal year 2008 shall be $85,000,000;

''(B) for fiscal year 2009 shall be $175,000,000;

‘‘(C) for fiscal year 2010 shall be $300,000,000; and

‘‘(D) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by

the amount of the quarterly assessment imposed on such manufacturer or importer under subsection (f) during each quarter of each fiscal year. Such notifications shall occur not earlier than 3 months prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification.

''(d) DETERMINATION OF USER FEE BY COMPANY MARKET SHARE.—

''(1) IN GENERAL.—The user fee to be paid by each manufacturer or importer of a given class of tobacco products shall be determined in each quarter by multiplying—

''(A) such manufacturer's or importer's market share of such class of tobacco products; by

''(B) the portion of the user fee amount

‘‘(e) DETERMINATION OF VOLUME OF DOMESTIC

‘‘(f) MEASUREMENT OF GROSS DOMESTIC VOLUME

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''tobacco product,'' after ''device,'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (c), by inserting ''tobacco product,'' after ''device,'';

(4) in subsection (e) (as amended by sections 2(c) and 3(b) of the Dietary Supplement and Non-prescription Drug Consumer Protection Act (Public

(9) by striking subsection (p) and inserting the following:

''(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(2).'';

(10) by striking subsection (q)(1) and inserting the following:

''(q)(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), or 908;

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or section 921; or

''(C) to comply with a requirement under section 522 or 913.'';

(11) in subsection (q)(2), by striking ''device,'' and inserting ''device or tobacco product,'';

(12) in subsection (r), by inserting ''or tobacco product'' after the term ''device'' each time that such term appears; and

(13) by adding at the end (as amended by section 4(a) of the Dietary Supplement and Non-

prescription Drug Consumer Protection Act (Public Law 109–462; 120 Stat. 3475)) the following:

''(jj) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

''(kk) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

''(ll)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any

products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).'';

(4) in paragraph (4) as so redesignated—

(A) in subparagraph (A)—

(i) by striking ''assessed'' the first time it appears and inserting ''assessed, or a no-tobacco-sale order may be imposed,''; and

(ii) by striking ''penalty'' and inserting ''penalty, or upon whom a no-tobacco-order is to be imposed,'';

(B) in subparagraph (B)—

(i) by inserting after ''penalty,'' the following: ''or the period to be covered by a no-tobacco-sale order,''; and

(ii) by adding at the end the following: ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''; and

(C) by adding at the end the following:

''(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.'';

(5) in paragraph (5) as so redesignated—

(A) by striking ''(3)(A)'' as redesignated, and inserting ''(4)(A)'';

(B) by inserting ''or the imposition of a no-tobacco-sale order'' after the term ''penalty'' the first 2 places such term appears; and

(C) by striking ''issued.'' and inserting ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.''; and

(6) in paragraph (6), as so redesignated, by striking the term ''paragraph (4)'' each place such term appears and inserting ''paragraph (5)''.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(D)''; and

(B) by striking ''device.'' and inserting the following: ''device, and (E) Any adulterated or misbranded tobacco product.'';

(2) in subsection (d)(1), by inserting ''tobacco product,'' after ''device,'';

(2) in subsection (a)(1)(B), by inserting ''or tobacco product'' after the term ''restricted devices'' each place such term appears; and

(3) in subsection (b), by inserting ''tobacco product,'' after ''device,''.

(h) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting ''tobacco products,'' after ''devices,''.

(i) SECTION 709.—Section 709 (21 U.S.C. 379) is amended by inserting ''tobacco product,'' after ''device,''.

(j) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''tobacco products,'' after the term ''devices,'' the first time such term appears;

(B) by inserting ''or section 905(j)'' after ''section 510''; and

(C) by striking the term ''drugs or devices'' each time such term appears and inserting ''drugs, devices, or tobacco products'';

(2) in subsection (e)(1), by inserting ''tobacco product,'' after ''device,''; and

(3) by adding at the end the following:

' ' ' ( )
' ( )

''(p)(1) Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

''(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

''(B) the public health implications of such exports, including any evidence of a negative public health impact; and

''(C) recommendations or assessments of policy alternatives available to Congress and the Executive Branch to reduce any negative public health impact caused by such exports.

''(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.''.

(k) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(b)) is amended—

(1) by striking ''and'' after ''cosmetics,''; and

(2) inserting ‘‘, and tobacco products’’ after ‘‘devices’’.

(l) GUIDANCE AND EFFECTIVE DATES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance—

(A) defining the term ‘‘repeated violation’’, as used in section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) as amended by subsection (c), by identifying the number of violations of particular requirements over a specified period of time at a particular retail outlet that constitute a repeated violation;

(B) providing for timely and effective notice to the retailer of each alleged violation at a particular retail outlet;

(C) providing for an expedited procedure for the administrative appeal of an alleged violation;

(D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(E) establishing a period of time during which, if there are no violations by a particular

retail outlet, that outlet will not be considered to have been the site of repeated violations when the next violation occurs; and

(F) providing that good faith reliance on the presentation of a false government issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

(i) adopting and enforcing a written policy against sales to minors;

(ii) informing its employees of all applicable laws;

(iii) establishing disciplinary sanctions for employee noncompliance; and

(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device.

(2) GENERAL EFFECTIVE DATE.—The amendments made by subsection (c), other than the amendment made by paragraph (2) of such subsection, shall take effect upon the issuance of guidance described in paragraph (1).

(3) SPECIAL EFFECTIVE DATE.—The amendments made by paragraph (2) of subsection (c) shall take effect on the date of enactment of this Act.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive'.

''WARNING: Tobacco smoke can harm your children'.

''WARNING: Cigarettes cause fatal lung disease'.

''WARNING: Cigarettes cause cancer'.

' ' ' ( )
' ( )

''WARNING: Cigarettes cause strokes and heart disease'.

''WARNING: Smoking during pregnancy can harm your baby'.

''WARNING: Smoking can kill you'.

''WARNING: Tobacco smoke causes fatal lung disease in non-smokers'.

''WARNING: Quitting smoking now greatly reduces serious risks to your health'.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—

''(A) IN GENERAL.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Except as provided in subparagraph (B), each label statement shall comprise at least the top 30 percent of the front and rear panels of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent

of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(4).

''(B) HINGED LID BOXES.—For any cigarette brand package manufactured or distrib-

''(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco product manufacturer, importer, or distributor and is not altered by the retailer in a way that is material to the requirements of this subsection except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with this subsection.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL

yield shall comprise at least 20 percent of the area

advertisement; 22.5-point type for a 28 centimeter

alternating sequence in advertisements for each

SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201, is further amended by adding at the end the following:

''(d) C

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

''(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except

''(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco products manufacturer, importer, or distributor and that is not altered by the retailer unless the retailer offers for sale, sells, or distributes a smokeless tobacco product that is not labeled in accordance with this subsection.

''(b) REQUIRED L

graph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

''(A) comprise at least 20 percent of the area of the advertisement, and the warning area shall be delineated by a dividing line of contrasting color from the advertisement; and

''(B) the word 'WARNING' shall appear in capital letters and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black on a white background, or white on a black background, in

''(3) CIGARETTE AND OTHER TOBACCO PRODUCT CONSTITUENTS

tobacco products that are not labeled in accordance with the requirements of subsection (a).''.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPECTION.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as added by section 101, is further amended by adding at the end the following:

''SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPECTION.

''(a) ORIGIN LABELING.—The label, packaging, and shipping containers of tobacco products for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'sale only allowed in the United States.'

''(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.—

''(1) IN GENERAL.—Not later than 9 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, re-

ceives, packages, holds, exports, or imports tobacco products.

''(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit

ceives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.

''(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

''(1) NOTIFICATION.—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

''(A) imported, exported, distributed or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

''(B) imported, exported, distributed or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General of such knowledge.

' ' ' ( )
' ( )

''(2) KNOWLEDGE DEFINED.—For purposes of this subsection, the term 'knowledge' as applied to a manufacturer or distributor means—

''(A) the actual knowledge that the manufacturer or distributor had; or

''(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the ex-

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General