GOVERNMENT AGREEMENT NUMBER 426-2001

Guatemala, October 16, 2001

The Constitutional President of the Republic

WHEREAS:

Decree Number 90-97 by the Congress of the Republic and its amendments contained in Decree Number 50-2000 by the Congress of the Republic, Health Code, establishes that health promotion actions must be aimed at improving the level of health through the adoption of healthy lifestyles, with emphasis, among other measures, on preventing the use of substances which are damaging to health, particularly those which are addictive; and it contains provisions aimed at the participation of manufacturers, importers, marketers and advertisers in promoting programs to report on the risks of consuming substances damaging to health and especially the use of tobacco and the damage to health it entails.

WHEREAS:

To achieve the proper application of such provisions a regulatory framework is required that establishes the competency and responsibilities of each of those involved in authorizing the advertising done by the mass media, together with the packaging or wrapping for tobacco products.

WHEREAS:

According to the provisions of Article 244 of Health Code Decree 90-97 of the Congress of the Republic, it is incumbent upon the Executive Branch through the Ministry of Public Health and Social Welfare to issue regulations to regulate the provisions on advertising and tobacco use contained in the Health Code and its amendments.

THEREFORE:

With the authority of the duties conferred by Article 183 subsections a) and e) of the Political Constitution of the Republic of Guatemala, 244 of Decree 90-97 by the Congress of the Republic, Health Code, and 27 subsection j) of Decree 114-97 by the Congress of the Republic, Law of the Executive Branch.

HEREBY AGREES:

To issue the following:

"REGULATIONS FOR THE REGULATION, APPROVAL AND ADVERTISING AND PLACES OF USE FOR TOBACCO-RELATED PRODUCTS"

CHAPTER I GENERAL PROVISIONS.

ARTICLE 1. PURPOSE.

The purpose of this regulation is to create the provisions for Health Code Decree Number 90-97 by the Congress of the Republic and its amendments contained in Decree Number 50-2000 by the Congress of the Republic, in order to facilitate its application by the Ministry of Public Health and Social Welfare related to the advertising of tobacco products made in the social media, whether written, graphic, radio, television, electric or electronic, cinema and mobile units; the places permitted for its use; the packaging or wrapping of such products; and the rules that must be followed by the manufacturers, importers, distributors and advertisers of such products.

ARTICLE 2. BASIC GOALS.

Pursuant to the provisions of the Political Constitution of the Republic and the Health Code, basic goals of these Regulations are:

- a) Protect inhabitants' health with regard to risks entailed by the use of tobacco and its derivatives;
- b) Protect users and inhabitants in general against advertising that stimulates the use of tobacco-related products.
- c) Protect inhabitants regarding the places where such products are used.

ARTICLE 3. FIELD OF APPLICATION AND RESPONSIBILITY.

Individuals or legal entities, whether domestic or foreign, who produce, manufacture, import, distribute or market tobacco-related products and its derivatives, along with its advertising agent or intermediary, and the social media are subject to the obligations established in this Regulation.

El documento fue generado para el uso exclusivo de: (Francisco Quezada)

ARTICLE 4. RULES, PROCEDURES AND FORMS.

The General Office of Regulation, Oversight and Health Control shall be the office responsible for proposing and approving the technical policies and verifying their obedience, the design of administrative procedures and forms for the corresponding requests and the approval of advertising for tobacco-related products. Such forms must be clear, objective and of general compliance, showing the documents that must be attached to the application and resolution times.

ARTICLE 5. INSPECTIONS.

The General Office of the Comprehensive Health Care System – SIAS – henceforth simply called "SIAS Office", shall be responsible through the network of authorized health care establishments for the issuance of resolutions of approval about the places permitted for the use of tobacco-related products, the inspections considered necessary of the establishments subject to control and supervision and, the hours of their operation in order to verify compliance with this Regulation. The responsible owner or person must allow duly identified health officials to perform the inspections in their establishments. In the event of non-compliance, administrative procedures shall be undertaken as considered by Law.

It is also responsible for overseeing the social media used to advertise the products to which this regulation refers and must begin the administrative procedure according to the Health Code and its amendments and this Regulation. The Ministry of Public Health and Social Welfare through the SIAS Office may at any time require the report on advertising guidelines from any social media.

ARTICLE 6. TECHNICAL DEFINITIONS.

For purposes of applying these Regulations, the following is understood:

Advertiser: Individual or legal entity that uses the advertising media to promote any product or service with commercial, informative or business goals. That which is advertised through the publicity. Customer of an advertising agency or of a mass communications media in the country.

Advertise. Communicate through advertisements.

Advertisement. Communication aimed at the public whose purpose is to sell a product or service and create interest in something. A graphic, radio, television, cinematic or internet advertising message.

Arial Black Upper Case Number 12. A specific typographical design that establishes the size of the font.

Advertising Authorization. Permission or consent granted by the Ministry of Public Health and Social Welfare through the competent offices with the purpose of authorizing all advertising related to tobacco products that conforms to the Law's requirements.

Pack. Package that contains units of the product, which may be:

- a) Hard Pack: Prepared with cardboard of a semi-thick consistency.
- b) Soft Pack: Prepared with paper of a thin consistency.

Brand. "Any visually perceptible denominative, figurative, three-dimensional or mixed type that is suitable for distinguishing the products or services of one individual or legal entity from those of another". Emblem. "A figurative symbol that identifies and distinguishes a company, business establishment or entity."

Broadcast. The act of spreading tobacco product advertising messages through the different social media in places open to the reach of the general public.

Distributor. "Individual or legal entity that on its own behalf sells, distributes, promotes, dispenses or places goods consisting of tobacco products in their various presentations from a domestic or foreign individual or legal entity called a principal to whom it is tied by a contract for distribution or representation."

Free Distribution. Any activity involving the free distribution of tobacco products in any of its presentations, goods or services bearing the name or registered brand name of tobacco products.

Promotional Distribution. Any advertising marketing activity designed to increase sales that involve the free distribution of tobacco-related products, as well as any other good or service whose goal is promotion of the name or registered trademark of a tobacco product.

Packaging. Packing specifically designed for purposes of transporting tobacco products. Box or covering with which tobacco products that are to be transported are protected

Wrapper. Packaging unit containing the individual cigarette packs or different tobacco products.

Advertising Spaces. Time or area used to advertise a brand in the different social media.

Manufacturer. Individual or legal entity that prepares tobacco-related products for use, whether by hand or mechanically.

Story Board [Historia de Proyecto: Project Story]. Rough translation of the American term "Story board".

Warning Captions. Alternate warnings will be:

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- Smoking tobacco causes cancer.
- Use of this product causes cardiovascular disease.
- Use of this product causes cancer of the mouth and pharynx.
- Smoking tobacco causes abortions and fetal malformation in pregnant women.
- Use of this product causes lung cancer.

Social Media. All forms or mechanisms of social communication used to transmit any type of information, including advertising messages for tobacco-related products, electric or electronic ones, such as radio, television, cinema, newspapers, magazines, pamphlets or internet.

Importer. Individual or legal entity, owner or not of tobacco-related products, who brings such products into the country under his own responsibility or on his own.

Advertising. Group of media used to broadcast advertisements of a commercial nature.

Tobacco Products. Any article whose raw material is tobacco or tobacco derivatives, designed for consumption.

Promotion. Strategic activities by the tobacco-related product brands for a particular time period through the giveaway of prizes, raffles or discounts with the goal of raising a product's sales.

Written Advertising. All advertising made through documents, manuscripts, typed or printed letters that are disseminated through the internet, newspapers, magazines, flyers, billboards, supplements and special events programs.

Advertising through Graphic Media. Everything done by means of shapes, symbols or expressions pertaining to or related to writing or the press, that is disseminated through placards, posters, billboards, hangings, wall placards, display placards, banners, electronic media, internet and others.

Advertising through Radio Media. All advertising transmitted by national radio on its various frequencies, community radios, closed circuit and any other modality which may arise in the future.

Advertising through Televised Media. All advertising transmitted by local, national, closed circuit and cable television, prescribed to be transmitted within the country.

Advertising through Cinematic Media. All advertising projected in movie theaters or through similar media.

Advertising through Electric or Electronic Media. All advertising carried out through neon signs or the internet.

Advertising through Mobile Units. That broadcast on the public street by using any means of land, air or sea transportation.

Manufacturer's Monthly Production. The total of tobacco-related products for domestic production prepared during a time period ranging between four and five weeks.

Children's Programming. All programming or advertising transmitted by television or cable after six o'clock in the morning and before nine o'clock in the evening.

Tobacco. Plant from the solanaceae [nightshade] family that is used for the fabrication of tobacco products.

Font. Design and style of a letter type. For the application of this Regulation, it refers to Arial Black Font, whose number means its size.

CHAPTER II

OFFICES RESPONSIBLE FOR APPROVAL OF THE ADVERTISING FOR TOBACCO AND ITS PRODUCTS

ARTICLE 7. CREATION OF THE COMMISSION.

The Ministry of Health shall create a functional commission through Ministerial Agreement, henceforth called "The Commission", that will technically assist the Regulatory Department of Health and Environment Programs from the General Office of Health Regulation, Oversight and Control, henceforth called "Department of Health and Environment", on advertising matters and with preparing the rulings for the subsequent authorization of advertising tobacco-related products.

ARTICLE 8. AUTHORIZATION.

Pursuant to the provisions of Article 49, subsection a) of the Health Code, all advertising about tobacco and its derivatives that is done through any of the media, prior to being broadcast must have the technical opinion in writing of "The Commission", based on which the Department of Health and Environment shall issue the respective technical ruling. Prior to the broadcast of any advertising job on the matter, the media must exact advertising authorization from the advertisers.

ARTICLE 9. REQUEST FOR AUTHORIZATION.

Advertisers of tobacco products must request advertising authorization in writing from the Department of Health and Environment, which shall make the proper decision with technical assistance from "The Commission". The request must be accompanied by copies of the advertising material as follows:

- a) For radio material, it shall present the text of the radio script containing the piece to be evaluated; b) For televised material, it shall present two copies of the project relating to the advertisement to be evaluated;
- c) For advertising through cinematic media, it shall present two copies of the project relating to the advertising announcement to be evaluated.
- d) For printed material, it shall present two properly protected rough outlines. This provision is in effect for placards, print ads, advertising billboards, banners, flyers and pamphlets.

Each copy must be duly identified with the advertiser's name and the purpose of the advertising piece, which will be accompanied by a request for approval of the material.

ARTICLE 10. CRITERIA FOR APPROVAL.

Criteria for the approval of advertising related to this Regulation are the contents of subsections b), d), e) and f) of Article 49 of the Health Code and this Regulation. Such criteria must be applied for the corresponding consideration and authorization.

ARTICLE 11. APPROVAL.

Once the request is received that meets the demanded requirements, the Department of Health and Environment shall immediately move to call a meeting of "The Commission" so that within a period of no more than ten working days from the day following when the request was received, it will issue the corresponding technical ruling. The decision may or not approve the proposed advertising, as well as recommend changes to the advertising material submitted.

If the Department of Health and Environment's technical ruling is favorable, it shall immediately be sent the General Office of Regulation for it to issue the corresponding authorization.

ARTICLE 12. TERM FOR DECIDING AUTHORIZATIONS.

The term for the decision on requests including the requirements demanded by this Regulation shall be fifteen working days, according to the procedure in the previous article.

CHAPTER III

CHARACTERISTICS OF PACKAGING, WRAPPERS OR PACKS

ARTICLE 13. OBLIGATORY NATURE.

The failure of packaging, wrappers and packs of tobacco products sold in the country of Guatemala to obey the provisions of Article 49 of the Health Code and this Regulation is forbidden. Therefore, manufacturers and importers shall be the ones responsible for ensuring that products they produce or import into the country for sale therein obey the provisions included in the Law.

ARTICLE 14. PARTS OF A PACK.

For the purposes of applying this Regulation, the parts of cigarette packs shall be:

- a) Front. On cigarette hard packs, the front shall be considered the part where the pack opens. On cigarette soft packs, the front shall be considered the part where there is no overlap or glue line from the label. b) Side. On cigarette packs in any of its presentations the side shall be considered either of its two sides, right or left, when looking at it from the front.
- c) Back. Part opposite the front of the pack.

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ARTICLE 15. WARNING ON THE FRONT PART OF PACKS.

When dealing with the product pack, warning captions must be visible, written in the Spanish language, with at least 12-point upper case Arial Black font, clearly legible, and occupy twenty-five percent (25%) of the lower portion of the front panel of its package design or pack. In order to determine the twenty-five percent (25%) of the space used by the caption on the front portion of the package design or pack, the total length of the pack must be measured from its bottom edge to its top edge. This measurement shall be divided by four, and the lower space shall be the space the warning must occupy.

ARTICLE 16. WARNING ON THE SIDE OF THE PACKS' PRESENTATION.

One of the sides of the packs' presentation must show the warning in clear, visible font: USE OF THIS PRODUCT CAUSES SERIOUS HEALTH DAMAGE.

ARTICLE 17. OTHER WRAPPERS OR PACKAGING.

Regarding alternative warnings contained on other packaging or wrappers defined in Article 6 of this Regulation, they must be clear and visible as shown by law.

ARTICLE 18. ALTERNATING NATURE OF WARNING CAPTIONS.

Warning captions shall be alternatingly assigned on both packs and other wrapppers or packaging of tobacco products. Thus, the manufacturer must assign one of the warnings when beginning printing of the packs for fifty percent of the monthly production. Then consecutively after printing the first of the warnings, the second, third, fourth and fifth will be printed in an alternating fashion, until one hundred percent of the monthly production is completed, and all the warning captions have been included in the same percentages. The purpose of the above is so that the market will have all the warnings mixed simultaneously and proportionally.

CHAPTER IV

ADVERTISING OF TOBACCO AND ITS PRODUCTS

ARTICLE 19. HEALTH WARNINGS ON TOBACCO ADVERTISING.

Pursuant to the provisions of Article 49 subsection b) of the Health Code, manufacturers, importers, distributors and advertisers of tobacco products are obliged:

- a. In graphic media. Productivity of tobacco products made through graphic media shall bear on the upper portion one of the alternate health warnings shown in subsection b) of Article 49 of the Health Code, and on the lower portion the general warning that says, "Use of this product causes serious health damage". When inserted, each warning must occupy five percent (5%) OF THE ADVERTISING SPACE. THE TWO WARNINGS MUST OCCUPY A TOTAL OF TEN PERCENT (10%) OF THE ADVERTISING SPACE.
- b. In televised media. In televised advertisements advertisers must include at the beginning and end of the televised advertisement one of the warnings referenced by subsection b) of Article 49 of the Health Code through a fixed credit of no less than three seconds. While the commercial lasts, the warning selected from the subsection shall be alternated with the warning: "Use of this product causes serious health damage", through teletext throughout the advertisement on the lower portion of the screen. The warnings must not interrupt the emblems or brands.
- c. In radio media. Advertising of tobacco products made on the radio media through radio spots must include a verbalized sentence at the beginning and end with the general warning that says, problem of the problem of the problem of the problem of the radio media through radio spots must include a verbalized sentence at the beginning and end with the general warning that says, problem of the radio media through radio spots must include a verbalized sentence at the beginning and end with the general warning that says, problem of the radio media through radio spots must include a verbalized sentence at the beginning and end with the general warning that says, problem of the radio media through radio spots must include a verbalized sentence at the beginning and end with the general warning that says, problem of the radio media through radio spots must include a verbalized sentence at the beginning and end with the general warning that says, and the radio media through radio spots must include a verbalized sentence at the beginning and end with the general warning that says, and the radio media through radio spots are represented by the radio media through radio spots and the radio spots and the radio spots are represented by the radio spots and the radio spots are represented by the radio spots and the radio
- d. In written media. Advertising of tobacco products made through written media must have one of the alternate health warnings shown in subsection b) of Article 49 of the Health Code printed on the upper portion, and on the lower portion, the general warning that says: "Use of this product causes serious health damage". Each warning shall occupy five percent of the advertising space, achieving a total of ten percent.
- e. On advertising billboards. Advertising of tobacco products made through advertising billboards must have one of the alternate health warnings shown in subsection b) of Article 49 of the Health Code printed on the upper portion, and on the lower portion, the general warning that says: "Use of this product causes serious health damage". Each warning shall occupy five percent (5%) of the advertising space, achieving a total of ten percent (10%).
- f. In mobile units. Advertising of tobacco products done in mobile units through loudspeakers or any other medium. It must show at the beginning one of the alternate warnings begun in subsection b) of Article 49 of the Health Code and the warning at the end: "Use of this product causes serious health damage".
- g. In electric or electronic media. Advertising of tobacco products made through electric or electronic media must have one of the alternate health warnings shown in subsection b) of Article 49 of the Health Code printed on the upper portion of the ad, and on the lower portion, the general warning: "Use of this product causes serious health damage".

In cinemagraphic media. In advertisements in cinemas or other similar media, advertisers must include at the beginning and end of the advertisement one of the warnings referenced by subsection b) of Article 49 of the

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Health Code through a fixed credit of no less than three seconds. As long as the commercial is on, the warning selected from the subsection shall be alternated with the warning: "Use of this product causes serious health damage", through teletext throughout the advertisement on the lower portion of the screen. The warnings must not interrupt the emblems or brands. Such advertising may be authorized only in spaces aimed at adult events.

ARTICLE 20. MONITORING OF TOBACCO ADVERTISING.

The Minister of Health through the SIAS Office through the Offices of Health Areas are the ones responsible for monitoring compliance with provisions conerning the advertising of tobacco-related products, as follows:

a) Health Areas Offices, through environmental health inspectors, shall visit all establishments that sell tobaccorelated products. They shall inspect placards, advertising billboards and mobile units to determine whether the warnings have been incorporated into these advertising media, as well as on cigarette wrappers and packs as stipulated in Article 10, subsection a) of this Regulation. b) The SIAS Office shall be responsible for randomly monitoring radio and television stations to make sure they are obeying the provision on the advertising of tobacco-related products.

ARTICLE 21. SUPERVISION OF PROMOTIONAL LIMITATIONS TO THE ADVERTISING OF TOBACCO-RELATED PRODUCTS.

Environmental health inspectors from the Health Areas Offices shall be responsible for supervising the contents of Article 49, subsections g), h) and i) of the Health Code regarding the following bans:

- a) Ban on advertising that shows use. No direct use of tobacco products shall be shown in their advertising through human models, animated drawings, sports athletes or public persons; b) Ban on Outdoor Advertising. Advertising or propaganda for tobacco products may not be placed within a radius of five hundred (500) meters around entrances and exits of preschools, preprimary, primary, middle and university educational institutions, facilities or sports complexes, installations for hospital assistance or recreation centers.
- c) Radio and television advertising. Advertising of tobacco products by radio and television media shall not be made during children's hours;
- d) Written Advertising. All advertising is banned in written materials aimed exclusively at young people and children.

ARTICLE 22. PROMOTION OF TOBACCO HEALTH WARNINGS.

Those responsible for public and private establishments to which Article 51 of the Health Code refers shall prepare and reproduce advertising signs no smaller than six inches high by fourteen inches wide on self-adhesive cardboard or paper with the following messages:

- a) No smoking.
- b) No cigarettes sold to minors under eighteen (18) years of age.
- c) No cigarettes sold individually or loose.
- d) Use of this product causes serious health damage.
- e) Smoking area.
- f) Non-smoking area.

CHAPTER V

BREACHES, SANCTIONS AND PROCEDURES.

ARTICLE 23. BREACH AND SANCTION.

Failure to obey, through action or omission, by manufacturers, importers, distributors and advertisers of tobacco products and their derivatives of the provision on advertising matters contained in the Health Code, its amendments and this Regulation, shall be considered to be a health violation that will be sanctioned according to Law.

CHAPTER V

FINAL, TRANSITORY AND REPEALED PROVISIONS.

ARTICLE 24. EPIGRAPHS.

The epigraphs which precede the articles to this Regulation have no interpretative validity and may not be cited with respect to the content and scope of same.

ARTICLE 25. REPEAL

All regulatory provisions opposing this Regulation are hereby repealed.

ARTICLE 26. TERM.

This Regulation shall take effect on the day following its publication in the official

gazette.

LET IT BE KNOWN

ALFONSO PORTILLO

MINISTER OF PUBLIC HEALTH AND SOCIAL WELFARE MARIO R. BOLAÑOS DUARTE

GENERAL SECRETARY OF THE

OFFICE OF THE PRESIDENT OF THE

REPUBLIC

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