Seamons, Colleen

From: Tom Murphy <tom@thehia.org>
Sent: Wednesday, 27 April 2011 10:25 AM
To: standards management
Subject: FSANZ Application A1039
Attachments: %JAT_Holler-Bosy_THC_in_Hemp_Products.pdf

Importance: High

FSANZ Application A1039

1. Are you aware of any evidence that consumers believe that low THC hemp foods have psychoactive effects?

No. The Hemp Industries Association (HIA) was founded in 1992 and has been working since that time with its members, the media and consumers to counter these perceptions in the U.S.

2. Are you aware of any evidence that representations on low THC food (including labelling and advertising) mislead consumers by leading them to believe that low THC hemp foods have psychoactive effects when consumed?

No. HIA members pledge to conduct their business in the hemp industry within the HIA guidelines for ethical business, including accurate labeling.

3. Can you provide any evidence in addition to that presented in this consultation paper whether or not the consumption of low THC foods can return a positive test for a THC drug test?

The HIA created the TestPledge program http://testpledge.com to help consumers understand trace THC in hemp foods. With current seed-cleaning technology and the correspondingly low trace THC levels in hemp oil and hemp nut, producing a confirmed positive test result would require that unrealistically high amounts of hemp oil or hemp nut be eaten. please see the attached study "Delta9-Tetrahydrocannabinol Content of Commercially Available Hemp Products" which generally shows that trace THC in hemp foods has been reduced and that eating hemp foods "should not be considered as a realistic cause for a positive urine analysis result." (Final sentence of Results and Discussion, pp. 431)

4. Can you provide information on THC testing in Australia and NZ, particularly with regard to regulatory limits of THC that may be set?

No. We have no knowledge of THC testing protocols in Australia and New Zealand.

5. Can you provide information to indicate whether there will be an impact on the cost of testing for THC in humans that could arise from an approval of hemp foods?

The cost of testing for THC in humans will not be increased following an approval of hemp foods, simply because no false positives are likely to be encountered. Here in the U.S, where mandatory drug testing is much more widespread than in Australia, the issue was pushed a decade ago by the White House Office of National Drug Control Policy (ONDCP), as well as by some in the military, but it has become a non-issue.

6. Do you agree that there are adequate controls currently in place, or that would be achieved by imposing maximum limits for THC, to mitigate any risk of high THC Cannabis varieties entering the food supply?

The HIA believes that there is no risk of high THC cannabis entering the food supply. Hemp food is exclusively derived from hemp seed which is produced from oilseed and fiber varieties of Cannabis sativa, commonly referred to as industrial hemp, which are subject to regulatory testing to ensure low levels of THC.

7. Do you consider that trade practices legislation in Australia and New Zealand is sufficient to mitigate the potential risk that representations (including labelling and advertising) of hemp foods could suggest psychoactive properties relating to consumption of those foods? If not, what labelling and representations of hemp foods should be considered?

It is our understanding that the advertising standards in Australia are rather stringent and are quite adequate to prevent any false or misleading claims being made.

8. What is the potential opportunity costs for current producers of hemp crops if hemp foods continue to be prohibited?

Industrial hemp farming and processing was re-legalized in Canada in 1998. The industry tried to focus on both fiber and oilseed production, but the food and bodycare marketplace was where the growth was the greatest, especially after the development of techniques for removing the hull from the seed, processing seed cake into protein powder and creating non-dairy hemp milk.

9. What are the potential benefits to food manufacturers if hemp foods were approved for use?

Increasingly found on store shelves, shelled hemp seeds ("hemp nuts") and cold-pressed oil have exceptional nutritional benefits and rich flavor. They are used in salad dressings, nutrition bars, flour, breads, cookies, granola, meatless burgers, nut butter, protein powders, chips, pasta, coffee blends and frozen desserts. Virtually all hemp nut and oil in U.S. foods are imported from Canada.

An impressive 33 percent of the hemp nut is high-quality protein, providing all essential amino acids in a reasonable balance, making it an attractive component of a meat-free diet. Hemp also contains significant amounts of the vitamin E complex and trace minerals such as magnesium, iron, and manganese.

But hemp seeds are valued primarily for the exceptional fatty acid composition of their oil, which makes up 30 percent of the whole seed and 44 percent of the nut. Studies link many common ailments to an imbalance and deficiency of essential fatty acids (EFAs) in the typical Western diet: too much omega-6 and not enough omega-3.
Consuming sufficient omega-3 in the right EFA ratio has impressive benefits, including: reducing cholesterol, reducing the risk of atherosclerosis and sudden cardiac death, reducing the need for insulin among diabetics, decreasing the symptoms of rheumatoid arthritis, promoting mood improvement in bipolar disorders, and optimizing development in infants.

Hemp oil contains the most EFAs of any nut or seed oil, with the omega-3 and omega-6 EFAs occurring in the nutritionally optimal 1:3 ratio. As a bonus it offers the higher-potency omega derivatives GLA and SDA. Fish and fish oils are recommended because they provide the omega-3 derivatives SDA, DHA, and EPA. But concern over the contamination of fish by mercury and other environmental toxins has led the FDA to warn pregnant women and nursing mothers to restrict their fish intake. Hemp's omega profile means that using hemp nut and oil as a staple food is a good alternative to fish: One tablespoon of hemp oil in a shake, salad, soup, or sauce provides 3 grams of omega-3, more than the 2 grams per day recommended by the U.S.
National Institutes of Health.

Virtually all common vegetable oils, such as soy, corn, sunflower, safflower and olive oil offer a much less desirable omega balance, i.e., not enough omega-3. Even walnuts, touted in recent media due to the FDA's qualified endorsement of their omega-3 health benefits, contain significantly less omega-3 and in a lower ratio to omega-6 than hemp seed. Of the commodity vegetable oils, only flax seed contains more omega-3, but flax does not have hemp's optimal EFA balance. Because it is more easily digestible with a longer shelf life and a nutty natural flavor, hemp nut also offers a greater range of culinary options than flax seeds.

10. Are there likely to be any additional costs for food manufacturers wishing to supply hemp foods?

As with any industrial scale agriculture costs fluctuate. Hemp is a crop with relatively low chemical inputs, so some costs may actually be lower, especially after a period of learning new farming and production techniques specific to the crop.

11. Would the approval of low THC hemp foods increase the cost of food enforcement beyond what would be expected of the approval of any other substance added to food, or other food regulatory change?

No additional costs could be reasonably anticipated. Hemp seed, especially hulled hemp seed contains negligible quantities of THC.
Therefore, any food manufactured from these will also be virtually free of THC, making product testing unnecessary. If testing is considered necessary it would only be necessary to batch test at the first stage of production i.e. the seed producer, with all downstream producers covered by the certainty that their products would be compliant.

12. What other legislation would affect or be affected by approval of hemp foods?

There need be minimal changes to existing legislation. Although domestically produced hemp foods are preferred, minor modifications to the Customs regulations would need to be made to facilitate any import of food grade hemp seeds. The changes would be of a similar nature to the industrial hemp laws, where exemptions to existing restrictions were introduced without difficulty or problems.

13. Would the approval of hemp food have an impact on hemp regulations in Australia and New Zealand? Would industrial hemp destined for use in food require additional controls to those already specified in industrial hemp regulations?

Hemp seed is currently a legal item of commerce in Australia, currently being used in the manufacture of cosmetics and other topical products, as well as a pet food supplement. No additional controls could conceivably be required, especially when dealing with processed items incapable of germination, such as hulled seeds.

14. Would food manufacturers be required to be licensed under existing hemp regulations?

As stated above the current situation in Australia is that any person can receive and process seed and fibre without restriction, providing it has been produced by a licensed grower. This has been confirmed in NSW by the Department of Primary Industry. There is no conceivable need to add additional regulation to a system that is currently working adequately.

15. Would additional costs be incurred by government agencies responsible for granting licenses for the cultivation of hemp as a result of approval of hemp foods?

With the expansion of the current hemp industry by the addition of food production there would be an increase in the number of farmers receiving licenses. However, no additional costs would be incurred because the system as it is currently operates is based on cost recovery, by fees paid.

16. Can you identity risk management options that have not been considered in the impact analysis?

There is no actual risk associated with changing the regulation so no risk management options need be considered. Joining the world community and legalizing hemp foods for consumption in Australia and New Zealand poses no risk, but a win-win scenario for farmers, producers and consumers.

17. Can you identify any other costs and benefits for any of the risk management options considered in this paper?

Any costs associated with adding hemp food to the approved schedule would be zero or minimal. Risks are non-existent, while the benefits to farmers, processors and consumers would be great.

18. Do you have a view about the appropriate preferred regulatory options regarding the approval of hemp foods, based on benefits and costs?

Our preferred regulatory option is that of minimal intervention, leading to a rapid normalization of the hemp food industry. The stated aim of the food regulations is to protect the health and well-being of the people of Australia and New Zealand. This is best done by expediting the introduction of hemp foods, whose ample nutritional profile will greatly benefit the population. What the hemp industry is seeking is not radical or ground breaking change, but simply to join the world community in adopting a safe and beneficial food.

Sincerely,

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Read att →

Δ^9-Tetrahydrocannabinol Content of Commercially Available Hemp Products*

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Abstract

Δ^9-Tetrahydrocannabinol (THC) is the main psychoactive compound present in marijuana. THC can also be found, as a contaminant, in some commercially available hemp products marketed in health food stores and on the internet as a good source of essential fatty acids. The products range from oil to alcoholic beverages to nutritional bars to candies, with oil being the most popular and commonly available. The analytical results are separated into two groups, products tested prior to and after publication of 21 CFR Part 1308, "clarification of listing of tetrahydrocannabinols." The data presented are a summary of 79 different hemp products tested for THC. THC was separated by a liquid–liquid or solid–liquid extraction, depending upon the product matrix. THC concentrations range from none detected to 117.5 µg THC/g material. Typical limits of detection for the assay (depending on matrix) are 1.0–2.5 µg THC/g material. Products that were of aqueous base (beer, tea) had much lower limits of detection (2.5 ng/mL). No THC was detected in 58% of the products from group 1 and 86% of the products from group 2. The amounts indicate that THC levels in currently marketed hemp products are significantly lower than in those products available before 2003 and reported in previous studies. The results reported here may be used as a general guideline for the THC content of hemp products recently found in the marketplace today.

Introduction

Δ^9-Tetrahydrocannabinol (THC) is the main psychoactive compound present in marijuana. The primary metabolite monitored by the Department of Defense and the Health and Human Services forensic urine drug testing programs is 11-nor-Δ^9-THC-9-carboxylic acid. Marijuana and hemp, a genotypic variant, are nearly identical members of the genus, *Cannabis sativa*, and differ by the amount of THC produced by each variant (1). Hemp is generally identified as Cannabis strains that produce less than 1% (by weight) of the psychoactive compound THC. Additionally, hemp used for manufacturing or the food industry is legal for import and sale in the U.S. but currently remains illegal to grow. The majority of the hemp used by U.S. industry is grown in Canada under strict government control. Marijuana, on the other hand, is cultivated to contain in excess of 1–20% THC (2–6). THC is found in the oily resin produced and localized mainly in the leaves and flowering buds of the cannabis plant. There is presently no way to distinguish between THC ingested by use of illicit marijuana and that of licit hemp products.

THC affects the central nervous system causing behavioral symptoms which include relaxation, increased awareness of the senses and appetite, and distortion of the environment (7). Physiological effects of THC include increased heart rate, dry mouth and throat, increased appetite, and increased diastolic blood pressure. Absorption of THC is much slower when ingested orally as compared to smoking. This is evidenced by THC detection within seconds in the plasma via the smoking route, whereas plasma THC detection after oral ingestion is not reached until approximately 2 h. Bioavailability of THC through oral ingestion is only 6–18% compared to 18–50% via smoking (7). This difference is caused mainly by THC degradation in the acidic environment of the stomach in addition to first-pass metabolism in the liver. Pharmacokinetically, THC is lipophilic, highly protein bound and exhibits extensive tissue distribution, all leading to a large volume of distribution (8).

Hemp seeds represent the manufacturing starting point for the vast majority of hemp products marketed since the mid-1990s. Hemp seeds are a good source of essential fatty acids, primarily alpha-linolenic acid (omega-3) and linoleic acid (omega-6). They are also found in fish, flaxseed, rapeseed oil, pumpkin seeds, and sunflower seeds. Essential fatty acids (EFA) are necessary fats that humans cannot synthesize, so they must be obtained through diet. EFAs support the cardiovascular, reproductive, immune, and nervous systems. The human body needs EFAs to manufacture and repair cell membranes, enabling the cells to obtain optimum nutrition and expel harmful waste products (9). THC found in manufactured prod-

* Disclaimer: The opinion or assertions herein are those of the authors and do not necessarily reflect the view of the Department of the Navy, Army, Air Force, or the Department of Defense.

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ucts is present via contamination from resin produced in the leaves and buds that come into contact with the seed shell. Seed decontamination and manufacturing processes including wash steps and cold pressing for hemp products have improved since the mid-1990s, leading to the much lower THC concentrations currently found in today's commercial products.

The presence of THC in these products has been a source of concern for the military and other workplace drug-testing programs. Ingestion of hemp products has been historically used as a defense in military and civilian trials for many years and continues today despite decreased concentrations of THC in hemp products (10–12). The Division of Forensic Toxicology, Armed Forces Institute of Pathology is often asked to analyze hemp products to determine their THC content in addition to rendering an opinion as to whether or not this THC concentration could be a reasonable cause for a positive THC metabolite urine analysis result. Over the past several years, the laboratory has analyzed 79 different products; the following is a summary of these results.

Experimental

Chemicals and reagents

All solvents were high-performance liquid chromatography (HPLC)-grade and purchased from Fisher Scientific (Pittsburgh, PA). Bis(trimethylsilyl)trifluoroacetamide (BSTFA) with 1% TMCS was purchased from Aldrich (Milwaukee, WI). Methanolic standards of THC and THC-d_3 were purchased from Cerilliant (Round Rock, TX).

Sample preparation and extraction

Hemp products were analyzed by a liquid–liquid (oil) or solid–liquid (seeds) extraction depending upon the matrix of the product. The amount of product extracted varied depending on the material: 250 mg for oil and 500–1000 mg for other products. A matrix match standard curve was used for all quantitative assays. For example, flax seed oil was used as the matrix for hemp oil and seed products, and a granola bar was used for hemp bar analysis. Four milliliters of 0.2 N methanolic potassium hydroxide (KOH) was added to the sample. This was followed by washing with hexane four separate times, with the upper organic layer discarded to waste. For solid hemp products, a homogenization step was added after the addition of the methanolic KOH by using a Polytron homogenizer (Brinkmann, Littau, Switzerland). The final wash with hexane included the addition of 1 mL deionized water to reduce methanol's limited miscibility with hexane. Water reduces the miscibility and forces the hexane out of the methanolic solution. The top organic layer was discarded and the solution is made acidic with 1.5 mL of 1 M hydrochloric acid (HCl). THC was then extracted into 3 mL of 10% ethyl acetate in hexane. The solution was mixed and centrifuged for 5 min. The upper organic layer was transferred to clean tubes and evaporated to dryness under nitrogen at 55°C. Samples were derivatized using 50 µL of BSTFA at 70°C for 20 min. Samples were removed from heat, allowed to cool, and transferred to properly labeled gas chromatography–mass spectrometry (GC–MS) vials, and capped.

Instrumental analysis

GC–MS analysis was performed using either an Agilent (Palo Alto, CA) 5890 or 6890 GC coupled to a 5972 or 5973 MS. The GC column was a J&W DB-5MS (20 m × 0.18-mm i.d. × 0.18 µm, Rancho Cordova, CA) with helium as the carrier gas maintained at a constant flow of 1.0 mL/min. One-microliter split injections were made with the injector temperature held at 250°C using a 4-mm inlet liner with deactivated glass wool. An

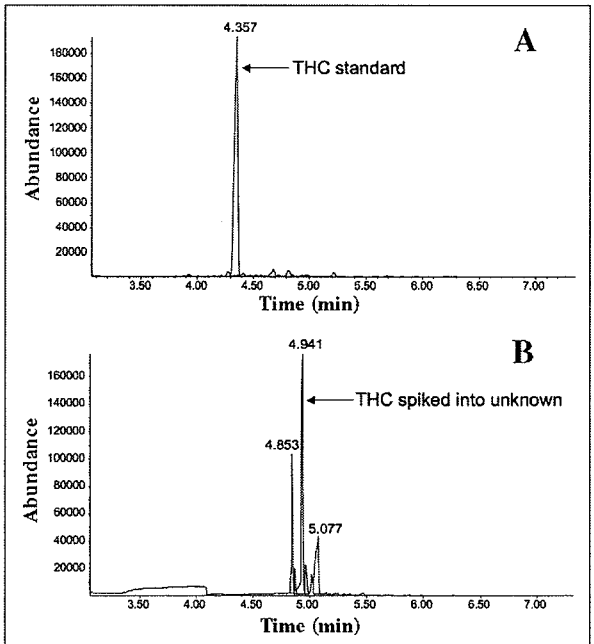

Figure 1. THC spiked in hand lotion for matrix matched standard curve (A), and THC spiked in a hemp tanning lotion (B).

Table I. Types of Hemp Products Tested

Type of Product	Number Tested
Oils	44
Bars	6
Lollipops	6
Seeds	4
Lotions	3
Protein	2
Gummy treats	2
Butters	2
Tablets	2
Teas	2
Beer	1
Chips	1
Cereals	1
Flours	1
Pretzels	1
Vodka	1
Total	**79**

initial GC oven temperature of 160°C was held for 1 min and ramped to 240°C at 40°C/min, from 240°C to 265°C at 10°C/min and then from 265°C to 300°C at 50°C/min with a final hold time of 1 min. The transfer line temperature was set to 280°C. The MS was operated in selected ion monitoring (SIM) acquisition mode. The SIM ions for THC and internal standard (THC-d_3) were (* denotes quantitation ion) *m/z* 303, 371*, 386 for THC and *m/z* 374*, 389 for THC-d_3. The ratio of *m/z* 386/389 was also used for quantitation if interfering matrix peaks from the oils affected peak symmetry of the primary quantitating ions.

Method validation

The linear range of the method was established with each extraction due to the variation in concentrations for each product. A multipoint standard curve with a typical range of 0–50 µg THC/g material was used for quantitation and prepared in a similar matrix. Typical limits of detection for the assay (depending on matrix) are 1.0–2.5 µg THC/g material. Products that were aqueous based (beer, tea) had much lower limits of detection (2.5 ng/mL). The various hemp products were tested as submitted and were analyzed with and without the addition of 10 µg of THC to each sample preparation. THC was added to the samples to ensure extraction efficiency within a given matrix and had acceptance criteria of ± 20%. Retention time shifts are also observed during analysis of the different matrices. The addition of THC to the unknown accounts for the retention time shifts that are sometimes outside of the generally accepted range of ± 2% (Figure 1). By addition of THC, it allows the shift to be monitored for each matrix and allow for accurate quantitation of the unknowns.

Results and Discussion

Table I shows a breakdown of the different types of products tested. Hemp products have expanded from mainly oil to many different products since the mid-1990s. The range of products includes several different beverages, nutritional bars, snacks, and candies. A possible cause for the wide range of available products could be to increase market share by providing hemp products for traditionally non-hemp foods. Another intent appears evident from provocative internet marketing, namely creating legal products that give the impression of illegality for a rebellious younger generation. This strategy, by advertising products that "contain marijuana" or are marijuana flavored, may aim to soften or blur the perception of marijuana as an illegal drug, making it more socially acceptable to market hemp products.

The results of THC analyses are listed in Tables II and III.

Table II. THC Content of Hemp Products Tested Prior to April 21, 2003

Manufacturer	Type	Date Tested	Results (µg/g)
Spectrum Essentials	Oil	20-Mar-98	36.0
Spectrum Essentials	Oil	20-Mar-98	117.5
Spectrum Essentials	Oil	20-Mar-98	36.4
Hempola	Oil	20-Mar-98	11.5
Hempstead	Oil	20-Mar-98	21.0
Health from the Sun	Capsule	20-Mar-98	48.6
Jones Juice Dave	Tea	28-Jul-01	< LOQ (5 ng/mL)
Spectrum Essentials	Oil	29-Aug-01	19
Govinda	Hemp Bar	1-Nov-01	< LOQ (1 µg/g)
Hempola	Oil	11-Dec-01	< LOQ (2.5 µg/g)
Manitoba Harvest	Oil	11-Dec-01	< LOQ (2.5 µg/g)
Manitoba Harvest	Seed	15-Jan-02	< LOQ (1 µg/g)
Hempola	Oil	25-Jan-02	< LOQ (2.5 µg/g)
Spectrum Essentials	Oil	25-Jan-02	23
Spectrum Essentials	Oil	25-Jan-02	29.5
Hempola	Flour	28-Jan-02	< LOQ (1 µg/g)
Spectrum Essentials	Oil	19-Feb-02	2.9
Spectrum Essentials	Oil	19-Feb-02	19.3
Cannabia	Beer	12-Apr-02	ND
Spectrum Essentials	Capsule	12-Apr-02	4.8
Spectrum Essentials	Capsule	12-Apr-02	22.8
Mum's	Oil	11-Jul-02	7.6
Unlabeled	Capsule	11-Jul-02	3.5
Hempola	Oil	11-Jul-02	13
Spectrum Essentials	Capsule	11-Jul-02	68.5
HempNut	Hemp Bar	22-Jul-02	ND
HempStead	Oil	7-Aug-02	12.6
Manitoba Harvest	Oil	7-Aug-02	< LOQ (2.5 µg/g)
Spectrum Essentials	Capsule	9-Aug-02	8.1
Hempola	Oil	14-Aug-02	4.9
Spectrum Essentials	Oil	14-Aug-02	< LOQ (2.5 µg/g)
HempNut	Oil	19-Sep-02	90.4
Orphee	Oil	19-Sep-02	< LOQ (2.5 µg/g)
Hemp Oil Capsules	Capsule	29-Nov-02	< LOQ (2.5 µg/g)
Spectrum Essentials	Capsule	29-Nov-02	5.2
Nutiva Hemp Seed	Bar	30-Dec-02	ND
Nutiva Hemp and Date	Bar	30-Dec-02	ND
Appalachian Blue Ridge	Cereal	30-Dec-02	ND
Spectrum Essentials	Oil	16-Jan-03	ND
Spectrum Essentials	Oil	16-Jan-03	ND
HempNut	Seed	25-Feb-03	< LOQ (1 µg/g)
HempNut	Butter	25-Feb-03	< LOQ (1 µg/g)
Manitoba	Butter	25-Feb-03	ND
Hempzel	Pretzel	26-Feb-03	ND
Ruth's	Chips	18-Mar-03	ND
Hempola	Oil	18-Mar-03	< LOQ (2.5 µg/g)
Hempola	Oil	18-Mar-03	15.2
Manitoba Harvest	Oil	25-Mar-03	ND
Manitoba Harvest	Oil	25-Mar-03	ND
HempNut	Oil	2-Apr-03	6.9

Table III. THC Content of Hemp Products Tested Post April 21, 2003

Manufacturer	Type	Date Tested	Results (µg/g)
Min Tong Company	Tablets	26-Jun-03	ND
Nutiva	Oil	29-Jul-03	7.8
Nutiva	Bar	28-Oct-03	ND
HempNut	Bar	28-Oct-03	ND
Living Harvest	Oil	28-Oct-03	ND
Nutiva	Oil	6-Feb-04	7.4
Chronic Candy	Lollipops	11-Mar-04	ND
Chronic Candy	Gummys	12-Mar-04	ND
Unlabeled	Seed	8-Jul-04	ND
Prairie Emerald Oil	Capsule	8-Jul-04	ND
Hempz Suntan Lotion	Lotion	19-Jul-04	ND
Hempola	Oil	30-Jul-04	ND
Viridian	Oil	30-Jul-04	7.5
Lor Special Drinks	Vodka	27-Aug-04	ND
Swiss Cannabis	Tea	8-Sep-04	ND
Manitoba Harvest	Protein	4-Feb-05	ND
Zand Herbal Formulas	Tablets	4-Feb-05	ND
Nutiva	Oil	10-May-05	ND
Nutiva	Oil	10-May-05	ND
Kiss My Face Corp.	Lotion	13-Jun-05	ND
Emerald Bay	Lotion	3-Feb-06	ND
Chronic Candy	Gummys	10-Jan-07	ND
Chronic Candy	Lollipop	10-Jan-07	1.04
Chronic Candy	Lollipop	10-Jan-07	< LOQ (1 µg/g)
Chronic Candy	Lollipop	10-Jan-07	< LOQ (1 µg/g)
Chronic Candy	Lollipop	10-Jan-07	< LOQ (1 µg/g)
Chronic Candy	Lollipop	10-Jan-07	< LOQ (1 µg/g)
Manitoba Harvest	Seed	1-Mar-07	ND
Nutiva	Protein	13-Jun-07	ND

Table II represents products tested prior to the publication of the Drug Enforcement Agency and Department of Justice's *Federal Register* 21 CFR Part 1308, "clarification of listing of tetrahydrocannabinols." This ruling stated that both natural and synthetic THC be listed as Schedule I drugs of the Controlled Substances Act (13). Table III represents products tested post 21 CFR Part 1308. Product manufacturer is listed as well as type of product tested.

Several other products were tested and excluded from the list for several reasons: they were adulterated (discolored, presence of particulate matter), unlabeled, or not commercially available. Two such products were candy bars manufactured by Tainted Truffles. These products, labeled as "Buddafinga" and "Stoners", contained significant amounts of THC (496 and 360 µg/g, respectively) (14). Other products excluded from the study range from oil received unsealed with leaf material present to homemade bread made with marijuana.

Results of the hemp products tested indicate the amount of THC present in commercially available products is significantly less in products available today than those reported in the past (15–22). As a result, the probability that these products will produce urine THC metabolite levels greater than the DoD and HHS confirmation cutoff of 15 ng/mL is significantly reduced and should not be considered as a realistic cause for a positive urine analysis result.

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