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**USE OF EPHEDRA-CONTAINING PRODUCTS IN THE U.S. POPULATION:
DATA FROM THE SLONE SURVEY**

A Comment Submitted to FDA Docket No. 95N-0304

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There has been considerable recent public concern about the potential dangers of products containing ephedra, but little hard information about how commonly these products are actually used in the U.S. population. Here we provide population-based data on this important question from the Slone Survey,¹ an ongoing survey conducted by the Slone Epidemiology Center (SEC) of Boston University.

The Slone Survey

The Slone Survey is a population-based random digit dialing (RDD) interview survey of medication use, covering the entire U.S. except for Alaska and Hawaii. Residents of households in the 48 contiguous states and District of Columbia are eligible for inclusion. Not eligible are those without telephones; residents of nursing homes, rehabilitation hospitals, or “group homes” (e.g., halfway houses); and individuals in prisons, military barracks, or college/university dormitories without telephones in individual rooms (unless reached at a residential phone number while home on leave or vacation). At each contacted residential number, one individual in the household is selected for interview by a computer-generated random number procedure. Subjects aged 14-17 years are interviewed only with the permission of a parent or guardian; for children under the age of 14, and subjects incapable of responding to the questions because of mental retardation or conditions such as Alzheimer’s disease, a surrogate (parent, spouse, or caretaker) is interviewed.

Information obtained includes age, sex, race, years of education, income, whether the subject has health insurance with prescription coverage, zip code of residence, and for women aged 18-50 years, pregnancy status (including due date or last menstrual period). All “medications” taken in the previous week, including prescription and nonprescription drugs,

vitamins, minerals, herbal preparations, and other natural supplements, are recorded. Wherever possible the names are confirmed from the product packages. A list of reasons for use (e.g., pain/headache/backache, depression/tension/emotional disorders) is read to elicit recall of other drugs, particularly OTC medications and dietary supplements. The following information is obtained for each product: reason for use, route of administration, number of days taken in the week before the interview, and total duration of the present episode of use.

The survey data provide a comprehensive picture of actual medication *use* (as opposed to sales or prescription information) in the U.S., including nonprescription drugs and herbal preparations. Because the survey is ongoing, it is possible to evaluate seasonal patterns and trends over time; the data also include usually unavailable information such as the individual's perceived reason for use. As of the end of December 2002, there were 10,474 interviewed subjects available for analysis, of whom 8,504 were at least 18 years of age and 1,970 were less than 18. The total participation rate was 67%, which is high even for academic RDD surveys,² and the participants have been shown to be representative of the U.S. population.¹

Use of Ephedra-Containing Products

As shown in Table 1, the overall one-week prevalence of use of any ephedra-containing products was 0.9% among adults. The highest usage was 1.4% in women aged 18-44. Use was lower in men, and declined with age in both men and women, to 0.2% of subjects aged at least 65 years. There was no use identified in children.

Time trends in overall use among adults are shown in Table 2. Because relatively few interviews were conducted in 1998, data from 1998 and 1999 are combined. There was a steady increase in the prevalence from 1998-99 to 2001, from 0.4% to 1.5%; in 2002 it declined to 1%.

Table 3 shows the reasons for use of ephedra-containing products among adults. Over half the use (52%) was for weight loss, with the next most common category being “energy,” at 28%; possibly related to that is “metabolic,” at 8%. All other other reasons had a frequency of less than 10% of the use.

The specific products taken are shown in Table 4. By a considerable margin, the most common was Metabolife 356, accounting for 34% of the use, followed by Xenadrine RFA-1 at 13%. None of the other individual products accounted for more than 8% of the use.

Comment

The Slone Survey data suggest that about 1% of the U.S. adult population is currently taking products containing ephedra, primarily for weight loss. With a total adult population of approximately 209 million, that translates to about two million users, which indicates the potential magnitude of any public health problems caused by these products. Concerns have also been raised about use in the pediatric population; while it is reassuring that we did not find any users under the age of 18, teenagers may be reluctant to admit their use, particularly if the products were obtained illicitly, and if the interview was completed by a parent s/he would not necessarily know about such use. Thus, some underestimation of pediatric use is possible. Otherwise, with the demonstrated similarity of the Slone Survey population to the U.S. population¹ and the high participation rate, we believe that the data are an accurate reflection of ephedra use among noninstitutionalized adults in this country.

References

1. Kaufman DW, Kelly JP, Anderson TE, Rosenberg L, Mitchell AA. A comprehensive population-based survey of medication use in the United States: the adult population. *Pharmacoepidemiol Drug Saf* 2000;9(S1):S60.
2. O'Rourke D, Johnson T. An inquiry into declining RDD response rates. Part III: a multivariate review. *Survey Res* 1999;2-3:1-3.

THE SLONE SURVEY

Table 1

Use of Ephedra-Containing Products in the U.S., 1998-2002

		No.	(%)*
Adults (8504 interviews)		71	(0.9)
Males	18-44 years	18	(0.9)
	45-64 years	5	(0.4)
	≥65 years	1	(0.2)
Females	18-44 years	30	(1.4)
	45-64 years	15	(1.1)
	≥65 years	2	(0.2)
Children <18 (1970 interviews)		<i>No users</i>	

*Percents adjusted for household size.

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Table 2

Time Trends in the Use of Ephedra-Containing Products Among U.S. Adults*

	No.	(%)†
1988-99 (2600 interviews)	10	(0.4)
2000 (2275 interviews)	19	(0.9)
2001 (1876 interviews)	26	(1.5)
2002 (1753 interviews)	16	(1.0)

*Based on data collected in 1998-2002.

†Percents adjusted for household size.

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Table 3

Reasons for Use of Ephedra-Containing Products Among U.S. Adults*

Reason	No.	(% of Users)
Weight loss	37	(52)
Energy	20	(28)
Metabolic	6	(8)
Diet supplement	5	(7)
Body building/strength	3	(4)
Other†	4	(6)

*Based on data collected in 1998-2002.

†Includes lower respiratory symptoms, recommended by friends, arthritis, allergy (1 each).

THE SLONE SURVEY

Table 4

Specific Ephedra-Containing Products Used by U.S. Adults*

Reason	No.	(% of Users)
Metabolife 356	24	(34)
Xenadrine RFA-1	9	(13)
Hydroxycut	6	(8)
Natural Trim	4	(6)
Metab-O-Lite	3	(4)
Women's Ultra Mega	2	(3)
Ripped Fuel	2	(3)
Body Solutions Atomic Energy	2	(3)
Tri-Chromaleane	2	(3)
Yellow Jacket	2	(3)
Diet Fuel	2	(3)
Metabolift Thermogenic Formula	2	(3)
All others†	15	(21)

*Based on data collected in 1998-2002.

†Includes Allercalm, Berry Trim Plus, Calorslim 2000, Creabolic Fizz, Dexatrim Results, GNC Optidrene, Metaboless, Thermolift, Adrena Lean, Ultra Diet Pep, Minithin 25/50, Pharmassure Energy Formula, Powerthin, Slim'n Up, Isis Herbal Cream (1 each).