

Pack is a dietary supplement containing, among other things, yohimbine and L-arginine that was marketed as a men's sexual performance enhancer.

According to the FTC complaint, the respondents failed to have substantiation for their claims that Focus Factor: (a) Improves the focus, memory, and concentration of healthy adults; (b) alleviates stress and combats the fatigue, irritability and mood swings that healthy adults experience; (c) makes children and teenagers feel more alert, focused, and mentally sharp; (d) improves students' ability to concentrate and their academic performance; (e) improves senior citizens' memory, mental clarity, and energy; (f) improves adults' ability to absorb information in books and to recall facts, figures and names; and (g) works in as little as one to ten days.

The complaint further alleges that the respondents failed to have substantiation for their claims that V-Factor Natural Pack is safe for virtually all men, and falsely represented that a clinical study of the V-Factor Natural Pack conducted by Dr. Carlon Colker proves that V-Factor is safe and is effective at improving sexual response and function.

Finally, the complaint alleges that the respondents: (1) Failed to disclose that certain of the consumer and expert endorsers who appeared in advertising for Focus Factor had material connections with the companies and individuals marketing the product, and that other consumer endorsements were solicited by the promise of a free 6-month supply of Focus Factor to those individuals whose testimonials were used in the company's advertising; and (2) misrepresented that certain radio infomercials were independent radio programs, not paid commercial advertising.

The proposed consent order contains provisions designed to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the order prohibits representations that Focus Factor or any substantially similar product (defined as any ingestible dietary supplement containing one or more specified ingredients): (a) Improves the focus, memory, and concentration of healthy adults; (b) alleviates stress, fatigue, irritability and mood swings in healthy adults; (c) makes children and teenagers feel more alert, focused, and mentally sharp; (d) improves students' ability to concentrate and their academic performance; (e) improves senior citizens' memory, mental clarity, and energy; (f) improves adults' ability to absorb information in books and to

recall facts, figures and names; or (g) works in as little as one to ten days, unless the claims are substantiated by competent and reliable scientific evidence.

Part II requires that the respondents possess competent and reliable scientific evidence to support any future claims about the safety, performance, benefits, or efficacy of any food, drug, or dietary supplement for: (a) The brain or any mental functions or processes (including, but not limited to cognitive function, memory, focus, learning or concentration), stress, anxiety, energy, mood or behavior, academic or business performance, longevity, age-related memory impairment or dementia; (b) sexual response, function, enhancement, or performance; or (c) the treatment, cure, mitigation, or prevention, of any disorder. Although the order does not prohibit the trade name "Focus Factor," it does require the respondents to have competent and reliable scientific evidence to substantiate any covered claims conveyed directly or by implication through the use of the product name.

Part III requires that the respondents possess competent and reliable scientific evidence to support any future claims that V-Factor Natural Pack or any product containing yohimbine is safe.

Part IV prohibits any misrepresentation of the existence, contents, validity, results, conclusions, or interpretations of any test or study, in connection with the marketing of sale of any product or program.

Part V requires disclosure of any material connection that exists between an endorser and the respondents or any other person or entity involved in marketing or selling the product or program that is the subject of the endorsement.

Part VI prohibits the creation or dissemination of any advertisement that misrepresents that it is not a paid advertisement, and requires that specific disclosures be included in any video or radio advertisement that is at least fifteen minutes in length.

Part VII permits any representation for any product that is permitted in labeling for such product by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

Part VIII provides for the payment of \$1 million to the Commission.

Part IX requires the respondents to retain certain records for five (5) years after the last date of dissemination of any representation covered by the order: (1) All advertisements and promotional materials containing the representation; (2) all materials relied upon in disseminating the representation; and

(3) all evidence in respondents' possession or control that contradicts, qualifies, or calls into question the representation or the basis for the representation.

Part X requires the respondents for ten (10) years to provide copies of the order to personnel having responsibilities relating to the subject matter of the order, and to obtain signed copies acknowledging receipt of the order.

Part XI requires that the Commission be notified of changes in corporate structure that might affect compliance obligations arising under the order.

Part XII requires that the individual respondents notify the Commission for five (5) years of any changes in employment that might affect their compliance obligations arising under the order.

Part XIII requires the respondents to file compliance reports with the Commission.

Part XIV provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 04-6461 Filed 3-22-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

The Secretary of Health and Human Services (HHS) has determined that the establishment of the National Science Advisory Board for Biosecurity (Committee) is necessary and in the public interest in connection with the duties of the Administration and that such duties can best be performed through the advice and counsel of such a group.

This Committee shall advise the Secretary of Health and Human Services; the Director, National Institutes of Health; and the heads of all federal departments and agencies that conduct or support life sciences research. The Committee will advise on and recommend specific strategies for the efficient and effective oversight of dual use biological research, taking into consideration both national security

concerns and the needs of the research community.

The Committee will be composed of not more than 25 voting, non-government subject matter experts, as well as ex officio members from federal departments and agencies that conduct or support life science research. Members will be appointed by the Secretary, HHS, in consultation with the heads of federal departments and agencies represented on the Committee in ex officio capacity.

Unless renewed by appropriate action prior to its expiration, the Charter for the National Science Advisory Board for Biosecurity will expire two years from the date of establishment.

Dated: March 15, 2004.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. 04-6355 Filed 3-22-04; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel; Science Education Partnership Award.

Date: June 29-30, 2004.

Time: June 29, 2004, 8 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Guo Zhang, PhD, MPH, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, Room 1064, Bethesda, MD 20817, 301-435-0812, zhanggu@mail.nih.gov.

(Catalogue of Federal Democratic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: March 16, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-6366 Filed 3-22-04; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: March 30, 2004.

Time: 12 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: One Democracy Plaza, 6701 Democracy Blvd., Bethesda, MD 20892.

Contact Person: Guo Zhang, PhD, MPH, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1064, Bethesda, MD 20814-9692, (301) 435-0812, zhanggu@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Conference Grants.

Date: March 31, 2004.

Time: 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: One Democracy Plaza, Office of Review, 6701 Democracy Blvd., 9th Floor Conference Room, Bethesda, MD 20892.

Contact Person: Sheryl K. Brining, PhD, Director, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, Rm.

1074, Bethesda, MD 20892-4874, (301) 435-0809, sb44k@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Center for Research Resources Special Emphasis Panel; Clinical Research.

Date: April 1, 2004.

Time: 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Guo Zhang, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, Room 1064, Bethesda, MD 20817, 301-435-0812, zhanggu@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: March 16, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-6367 Filed 3-22-04; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, "Blending Research and Practice".

Date: April 14, 2004.

Time: 9 a.m. to 4 p.m.