

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

13071



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# MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

CFSAN

For reporting by health professionals of adverse events and product problems

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Form Approved: OMB No. 0910-0291 Expires: 12/31/94 See OMB statement on reverse

FDA Use Only H Pad  
 Triangle unit sequence # **88327**  
**13071**

### Patient information

1. Patient identifier: [redacted]  
 2. Age at time of event: [redacted]  
 or Date of birth: [redacted]  
 3. Sex:  female  male  
 4. Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kgs

### Adverse event or product problem

Adverse event and/or  Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply):  
 death (mo/day/yr)  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event (mo/day/yr): **5/28/98**  
 4. Date of this report (mo/day/yr): **8/21/98**

### Describe event or problem

Presented to ER; diagnosed w/Bell's palsy by MD and given RX for oral steroids and discharged home. No follow-up available. Only product being taken was Metabolife 356 (see c)

I'm reporting simply because I found a report of Bell's palsy symptoms on your Nutritional Adverse Events System for a product containing similar ingredients.

### Relevant tests/laboratory data, including dates

NA \*see 2nd page for product ingredients

### Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Other medications: [redacted]  
 had a "cold" recently  
 IKDA  
 denies alcohol, tobacco

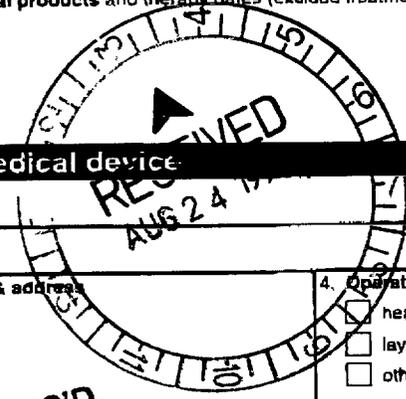
### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)  
 #1 **Metabolife® 356 Metabolife International**  
 #2 \_\_\_\_\_  
 2. Dose, frequency & route used  
 #1 **1.5 tabs tid**  
 #2 \_\_\_\_\_  
 3. Therapy dates (if unknown, give duration)  
 #1 **3 weeks**  
 #2 \_\_\_\_\_  
 4. Diagnosis for use (indication)  
 #1 **Desired weight loss**  
 #2 \_\_\_\_\_  
 5. Event abated after use stopped or dose reduced  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply  
 6. Lot # (if known)  
 #1 **N/A**  
 #2 \_\_\_\_\_  
 7. Exp. date (if known)  
 #1 **N/A**  
 #2 \_\_\_\_\_  
 8. Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply  
 9. NDC # (for product problems only)  
 #1 \_\_\_\_\_  
 #2 \_\_\_\_\_

10. Concomitant medical products and therapy dates (exclude treatment of event)

### D. Suspect medical device

1. Brand name  
 2. Type of device  
 3. Manufacturer name & address  
 4. Operator of device  
 health professional  
 lay user/patient  
 other:  
 5. Expiration date (mo/day/yr)  
 6. Model #  
 catalog #  
 serial #  
 lot #  
 other #  
 7. If implanted, give date (mo/day/yr)  
 8. If explanted, give date (mo/day/yr)



9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

### E. Reporter (see confidentiality section on back)

1. Name, address & phone #  
 [redacted]  
 2. Health professional?  yes  no  
 3. Occupation: **Pharmacist**  
 4. Also reported to:  
 manufacturer  
 user facility  
 distributor  
 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787  
 or FAX to: 1-800-FDA-0178

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# Metabolife International, Inc.™

Thank you for your interest in Metabolife 356

Metabolife 356 was formulated to raise the metabolism and create a thermogenic response, which in turn burns fat, not lean muscle. Because of this precise blending of herbs and other nutrients, you will immediately realize higher energy levels, which is normally not achieved while dieting and reducing caloric intake. In fact, many people take Metabolife 356 as an energy enhancer. Metabolife 356 is also formulated with chromium picolinate, which is proven to burn fat and decrease appetite without additional effort.

The herbal ingredients in Metabolife 356 include: Guarana, Ma Huang, Siberian Ginseng, Lecithin, Ginger Root, Damiana, Sarsaparilla Root, Goldenseal, Gotu Kola, Spirulina Algae, Bee Pollen, Nettle Leaf, and Royal Jelly. The exact amounts of each herb are proprietary but complete toxicology/safety testing has been done. The per tablet amounts of naturally occurring ephedrine (in Ma Huang) and caffeine (in Guarana) alkaloids are 12 mg and 40 mg, respectively. In addition to the herbs mentioned above there is 6 IU Vitamin E, 75 mg Magnesium Chelate, 5 mg Zinc Chelate, Bovine complex and 75 mcg Chromium Picolinate.

Metabolife 356 is produced with these thoughts in mind: SAFETY (when used as directed), QUALITY, and to provide you with the FINEST supplement available for your diet. Once you try Metabolife 356, we're sure it will become your dietary supplement of choice.

The dosage of Metabolife 356 is body weight specific, for example: 120 lb individual should take 1 tablet 2-3 times per day at 4 hour intervals beginning at one hour prior to breakfast, scaling up the dosage at 1/2 tablet increments for each 35 pounds body weight (e.g., 155 lbs = 1.5 tablets, 190 lbs 2 tablets, etc.) These are suggestive beginning dosages and should be adjusted for each individual. It is important to eat within an hour of the dosage (emphasize high fiber, avoid high density caloric foods like fats and sugars) and consume at least one pint of water between doses.

Cost for 90 tablets = \$49.95 (discounts for multiple bottles are as follows: 2 bottles = \$45.00 each, 3 bottles = \$42.95 each, 4 bottles = \$39.95 each, 5 bottles = \$37.95 each (tax and postage is included) Orders can be placed by calling 1-800-962-DIET (3438), through the Internet and by mailing a check to: Metabolife Int'l Inc 5070 Santa Fe Street, San Diego, CA 92109.

For more information and other Metabolife products, visit our web sites at [www.weightlossdiet.com](http://www.weightlossdiet.com) and [www.metabolife.com](http://www.metabolife.com).

We are so confident that you'll be absolutely pleased with Metabolife 356, we offer a full money back guarantee. If you are not satisfied with the results call our customer service department to receive a refund confirmation code and send back the unused portion (or just the bottle if empty) with your receipt and we will refund your money, no questions asked.

Please feel free to contact me if I can be of any further assistance.

Health Advisory Department  
[medical@metabolife.com](mailto:medical@metabolife.com)  
 (888) 301-3438 x216  
 (619) 490-5222 x216

5070 SANTA FE STREET • SAN DIEGO, CA 92109 • TEL (619) 490-5222 • FAX (619) 490-5233

Underlined compounds were the ~~same~~ <sup>also</sup> in the product I found in your nutritional database as potential cause of Bell's Palsy.

~~CTU~~ CTU 88327

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