DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: DEC 5 2000

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From: Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820

Subject: 75-Day Premarket Notification for New Dietary Ingredients

To: Dockets Management Branch, HFA-305

New Dietary Ingredient:	Glucose Metabolism Modulator (GMM)
Firm:	Van Drunen Farms, VDF FutureCeuticals
Date Received by FDA:	September 6, 2000
90-Day Date:	December 5, 2000

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on pubic display in docket number 95S-0316 after December 5, 2000.

Virginia K. Williams

for Felicia B. Satchell

95S-0316

RPT 84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

NOV 20 2000

Jeff Van Drunen
Vice President
Van Drunen Farms/VDF FutureCeuticals
R.J. VanDrunen & Sons, Inc.
300 West 6th Street
Momence, Illinois 60954

Dear Mr. Van Drunen:

This is in response to your letter submitted to the Food and Drug Administration (FDA) making a submission for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the act)). Your letter notified FDA of your intent to market a new dietary ingredient Glucose Metabolism Modulator (GMM), an extract from barley (*poaceae, hordeum vulgare*). FDA received your submission on September 6, 2000. For the reasons discussed below, we believe that GMM, as presented in your submission, is a drug under 21 U.S.C. 321(g)(1)(B)(section 201(g)(1)(B) of the act) because it is intended for treatment of non-insulin dependent diabetes mellitus.

You state in your submission "The ordinary condition of use would be as a natural plant derived extract for the aid of the normal human condition of [an] elevated blood glucose level. (non-insulin dependent diabetes mellitus)." You also maintain:

> The extract specifically binds to a thaumatin-like protein, and the composition can be orally administered in a dosage effective to decrease the blood concentrations of glucose. The composition has further been shown to reduce the concentration of blood lipids including triglycerides, fatty acids, HDL-cholesterol and LDL cholesterol.

(Notification at page 1).

Under 21 U.S.C. 321(g)(1)(B), a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. You indicate in your submission that you will suggest to consumers that GMM be used for the aid of an elevated blood glucose level (non-insulin dependent diabetes mellitus). As a result, your product is intended as treatment for non-insulin dependent diabetes mellitus and thus is a drug under 21 U.S.C. 321(g)(1)(B). See 21 CFR § 101.93(g). Accordingly, your product would be subject to regulation under the drug provisions of the act. If you wish GMM to be evaluated for its use in the treatment of non-insulin dependent diabetes mellitus, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

As we have stated above, GMM is a drug. Nonetheless, we have carefully considered the information in your submission concerning if a dietary supplement containing GMM, if it were able to be marketed as a dietary supplement, will reasonably be expected to be safe. We have significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing GMM will reasonably be expected to be safe. We explain our concerns below.

The submission does not describe the new dietary ingredient that is the subject of the submission, other than it is an "extract made from malted barley." As discussed above, 21 U.S.C 350b(a)(2) states that a dietary supplement containing a new dietary ingredient is adulterated unless there is a history or use or other evidence of safety establishing that it will reasonably be expected to be safe. The manufacturer must submit to FDA the information that is the basis for it having determined that the dietary supplement will be reasonably expected to be safe. It is not possible to have a reasonable expectation of safety without knowledge of the nature and identity of the new dietary ingredient. The description of your new dietary ingredient, that is, it is "an extract made from malted barley" does not address the specific qualitative and quantitative characteristics of the dietary ingredient that would enable a determination to be made that there is a reasonable expectation of safety. Such information is a necessary prerequisite to meeting the requirements set forth in 21 U.S.C 350b(a)(2).

Your submission contains evidence of history of use and other information that you assert is an adequate basis to conclude that the type of dietary supplement product containing the new dietary ingredient will reasonably be expected to be safe. With respect to history of use, you maintain that you were unable to find any information in the scientific literature that any form of barley is unsafe. As stated previously, under 21 U.S.C. 350b(a)(2) there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe. Under the act, the evidence of a history of use must

pertain to the dietary ingredient that is the subject of the notification. The fact that the source material (i.e., barley) may be safe does not provide a basis to conclude that a dietary supplement containing a dietary ingredient derived from the same source material which has been altered (i.e., an extract from malted barley) would be safe.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that GMM, when used under the recommended or suggested conditions of use in the labeling of your product, will reasonably be expected to be safe. In addition, because the information in your submission indicates that your product is a drug and not a dietary supplement, not only would your product be subject to regulation as a drug if marketed, but, even insofar as it might be argued that your product is a dietary supplement, it could be deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) (section 402(f)(1)(B) of the act). In any event, you are not prohibited from submitting a new pre-market notification for GMM under 21 U.S.C. 350b(a)(2), if you deem such resubmission appropriate.

Your submission will be kept confidential for 90 days from the date of receipt, September 6, 2000, and after December 5, 2000, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Should you have any questions concerning this matter, please contact us at (202) 205-4168.

Sincerely yours,

for Felicia B. Satchell
Director
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition

1221A

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
200 C St. SW
Washington, DC 20204

Premarket Notification – 21 CFR Sec. 190.6

Manufacturer:
VanDrunen Farms/VDF FutureCeuticals
R.J. VanDrunen & Sons, Inc.
300 West 6th Street
Momence, IL 60954
815-472-3545

The name of the new dietary ingredient that is subject of the premarket notification is :

GMM (a natural extract from Barley (poaceae, hordeum vulgare)

The description of the new dietary ingredient, **GMM** is:

GMM is patent pending natural product extract made from malted barley. The extract specifically binds to a thaumatin-like protein, and the composition can be orally administered in a dosage effective to decrease the blood concentrations of glucose. The composition has further been shown to reduce the concentration of blood lipids in cluding triglycerides , fatty acids, HDL- cholesterol and LDL cholesterol.

i). The level of use of the supplement would be suggested at 5 gms per day.

ii). No conditions of use are suggested or recommended on any labeling as this is a ingredient and not a finished supplement. The ordinary condition of use would be as a natural plant derived extract for the aid of the normal human condition of a elevated blood glucose level. (non-insulin dependent diabetes mellitus).

Enclosed is history of use and published information offered in support of the premarket notification of the new dietary ingredient, **GMM** :

Barley in many forms has been a food staple used for centuries. In our literature search we have not found any form of barley to unsafe to be used as a food staple or supplement in anyway. In more recent times it has been proven and even endorsed by the FDA and USDA that Barley and its components have many significant health benefits. In particular much study has been done on barley beta-glucans, a soluble fiber found in barley which lowers cholesterol. GMM like beta-glucans is a component of barley that has interesting health benefits. In addition to the fact that barley and its components are

generally accepted as safe , and to further ensure the safety of the GMM Barley extract, a Toxicology Study has been completed with GMM. This was done by Walter N. Shaw P.H.D. at Genetic Models Inc. and a copy of the toxicological study is enclosed.

Signature:

Jeff Van Drunen
Vice President
Van Drunen Farms/ FutureCeuticals
815-472-3545
jvandrunen@vandrunen.com

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3-21-2000 FF00-001 STUDY: TOXOCOLOGY STUDY WITH THE MALTED BARLEY EXTRACT

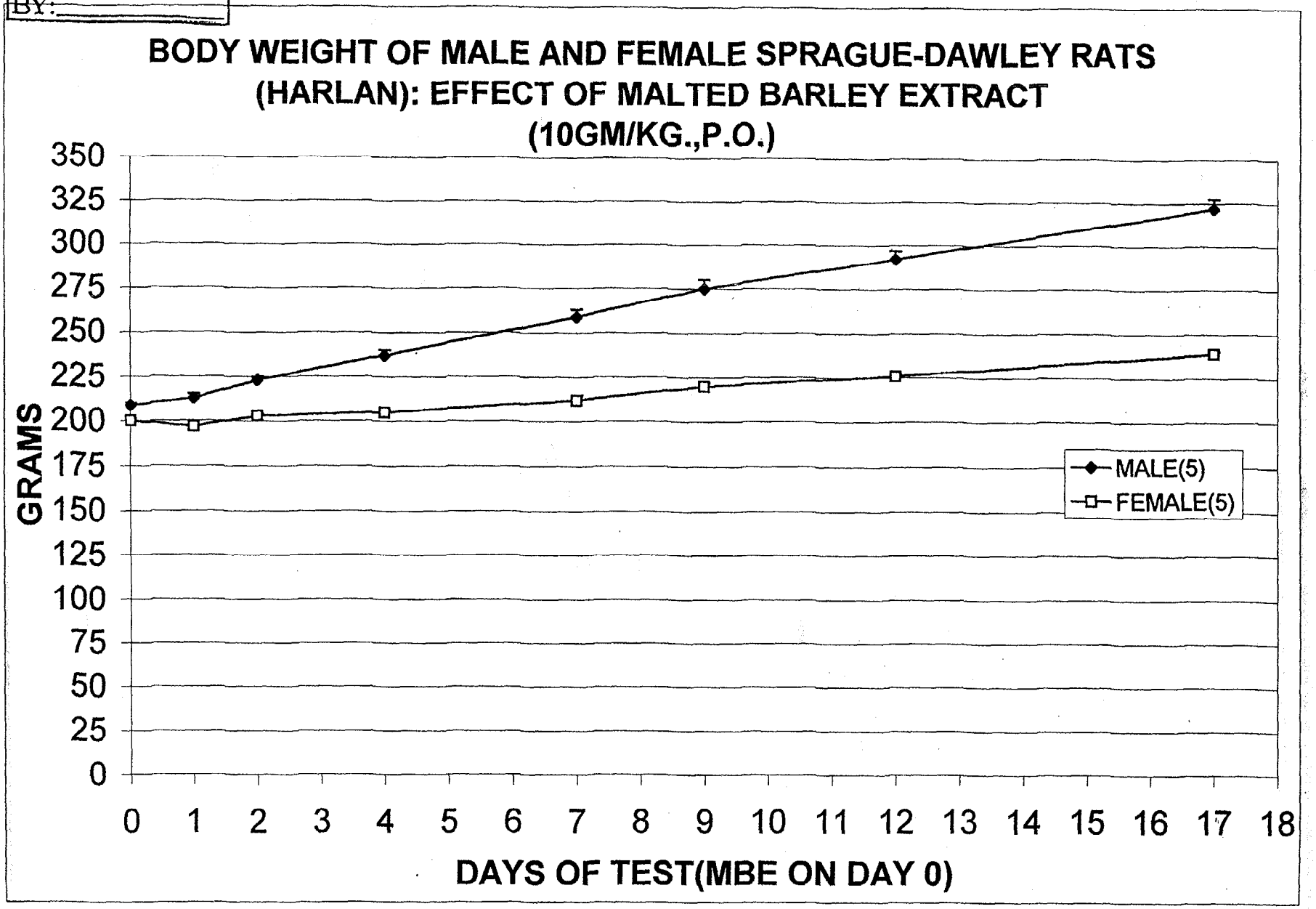
WE HAVE COMPLETED THIS STUDY ON 3-20-2000.

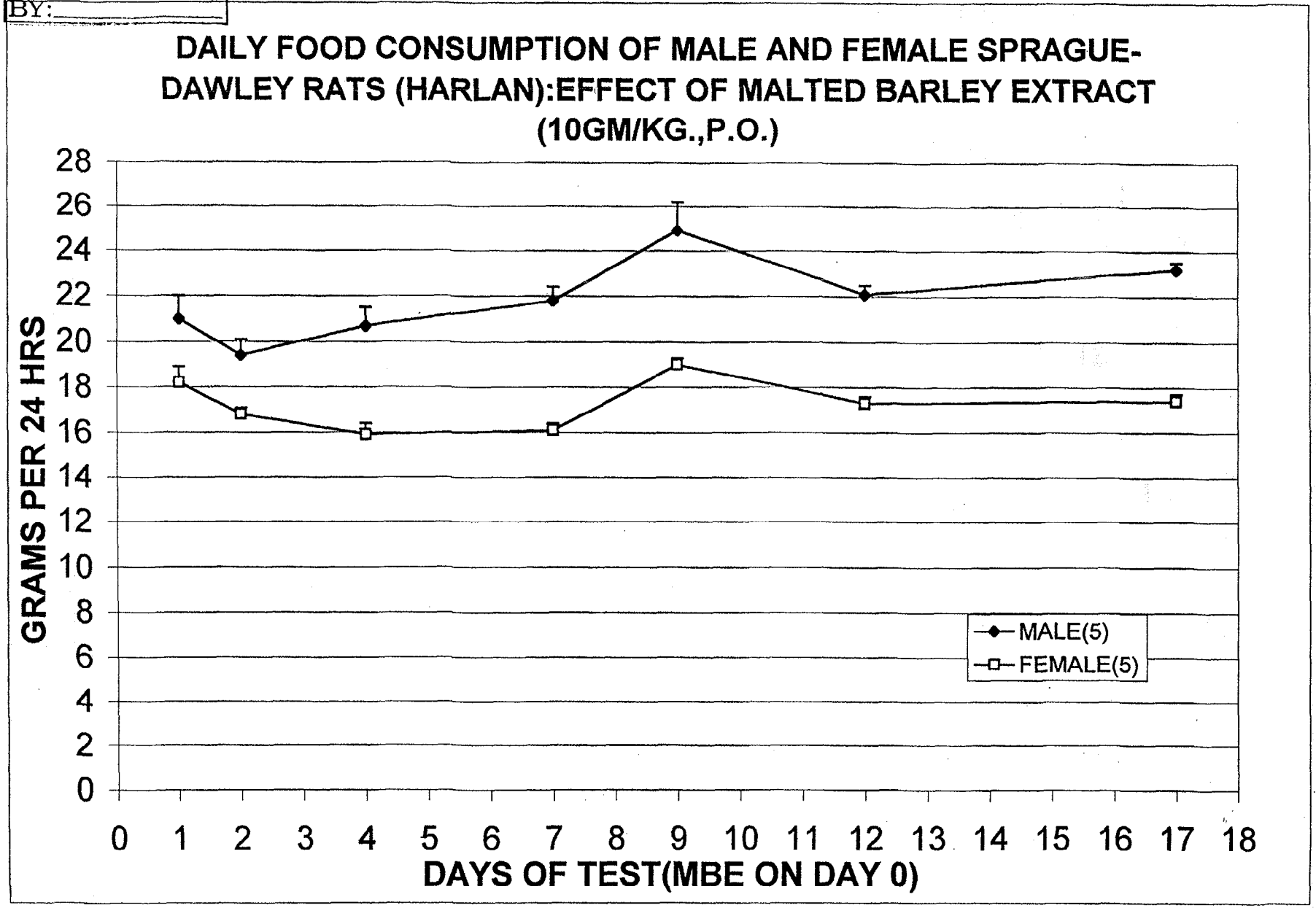
FIVE MALE AND FIVE FEMALE SPRAGUE-DAWLEY RATS (OBTAINED FROM HARLAN) WERE RECEIVED ON 3-1-2000 AND THE RATS PLACED IN INDIVIDUAL CLEAR PLASTIC SHOEBOX CAGES. THEY WERE HOUSED IN A SELF-CONTAINED, HEPA FILTERED BUBBLE UNIT. THIS WAS DONE TO PROTECT OUR ANIMAL FACILITIES FROM EXPOSURE TO RATS FROM AN OUTSIDE FACILITY. THE TECHNICIAN ENTERED THE BUBBLE FACILITY AT THE END OF THE DAY AND DID NOT ENTER ANY OTHER ROOM CONTAINING RATS THE REMAINDER OF THAT DAY. THE RATS WERE ALLOWED PURINA 5008 FOOD AND WATER AD LIBITUM. ON 3-3-2000, THESE RATS WERE WEIGHED AND GIVEN AN ORAL DOSE OF THE MALTED BARLEY EXTRACT (MBE) OF 10 GM/KG. THEY WERE OBERVED HOURLY FOR THE FIRST 8 HOURS AFTER THE ONE ORAL DOSE OF MBE. THERE WERE NO VISIBLE SIGNS OF CHANGE IN APPEARANCE AND ACTIVITY. THEREAFTER, ON DAYS 1, 2, 4, 7, 9, 12 AND 17 BODY WEIGHT WAS DETERMINED IN THE LATE AFTERNOON. ON THESE SAME DAYS FOOD AND WATER CONSUMPTION WAS MEASURED AND EXPRESSED AS THE MEAN INTAKE PER 24 HOURS FOR THAT DAY OR FOR A SEVERAL DAY PERIOD. AT NO TIME WAS THERE ANY NOTICEABLE CHANGE IN THE APPEARANCE, ACTIVITY OR VISIBLE HEALTH OF THESE RATS. ALL RATS SURVIVED. AT THE COMPLETION OF THE STUDY, EACH RAT WAS SACRIFICED USING A CARBON DIOXIDE INHALANT AND THE ABDOMINAL CAVITY OPENED AND INSPECTED. NO OBVIOUS ABNORMALITIES WERE FOUND.

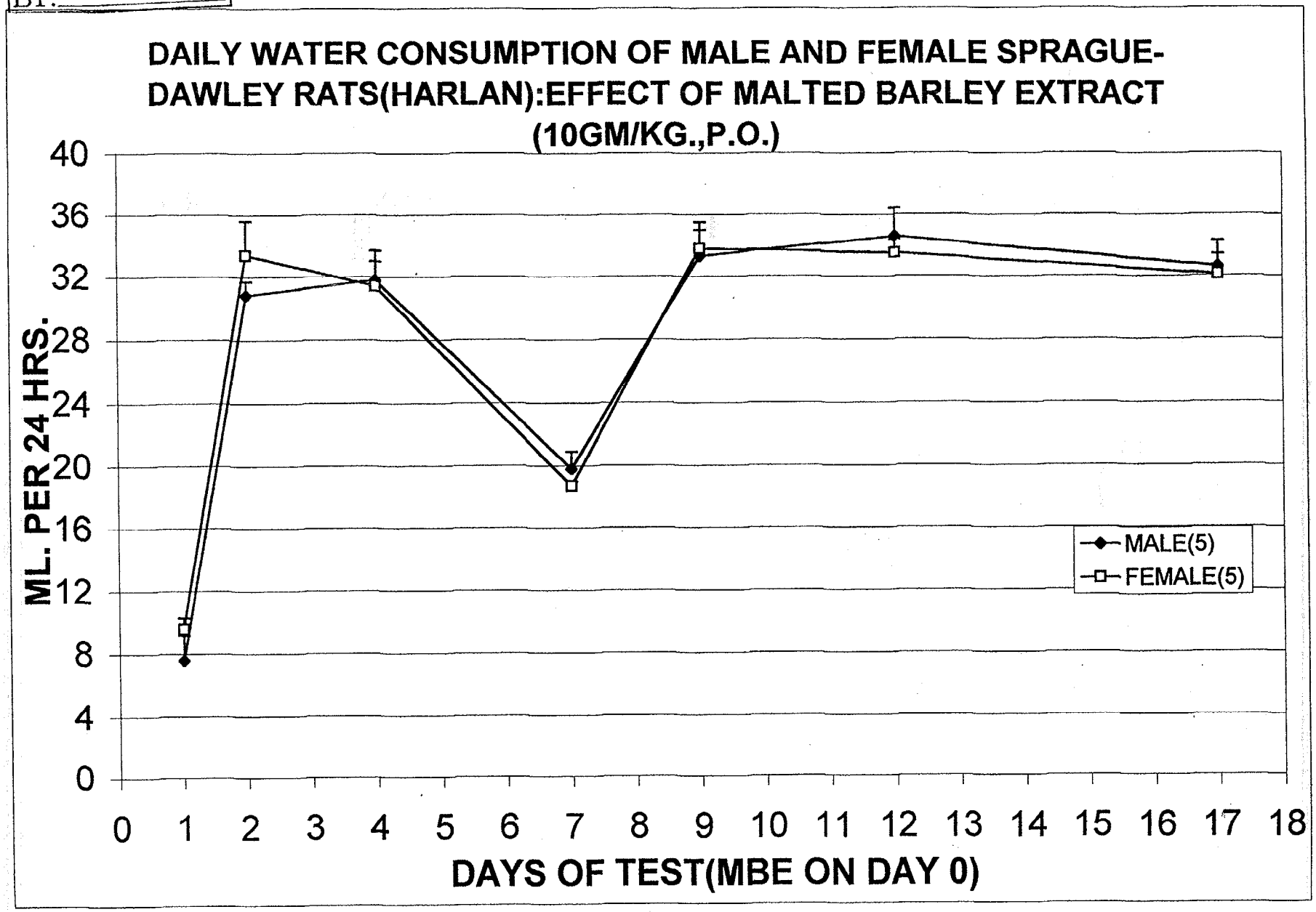
I HAVE PREPARED THREE GRAPHS SHOWING:

(1) CHANGE IN BODY WEIGHT
(2) CHANGE IN FOOD CONSUMPTION
(3) CHANGE IN WATER CONSUMPTION.
I HAVE NO REASON FOR THE DIP IN WATER CONSUMPTION OF BOTH GROUPS AT DAY SEVEN. BECAUSE THE VALUES AT DAYS 2, 4, 9, 12 AND 17 ARE VERY MUCH THE SAME, I THINK THE DAY 7 VALUE IS SPURIOUS.

WALTER N. SHAW, P H. D.
CONTRACT RESEARCH COORDINATOR
GENETIC MODELS INC.
P.O. BOX 68737
INDIANAPOLIS, IN. 46268-0737







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FUTURE CEUTICALS

Nutraceuticals from Van Drunen Farms

PRODUCT SPECIFICATION

FutureCeutical GMM

PRODUCT DESCRIPTION

FutureCeutical GMM (Glucose Metabolism Modulator). A natural proprietary extract from barley classified as *Hordeum valgare*.

GENERAL REQUIREMENTS

Material and workmanship shall be of good quality and the product prepared in accordance with good commercial practice under strictly sanitary conditions.

PHYSICAL CHARACTERISTICS

Color: FutureCeutical GMM shall be tan to white in color.
Flavor: FutureCeutical GMM shall have a flavor typical of Barley.
Size: 100% through a U.S. #20 Screen

MICROBIOLOGICAL REQUIREMENTS

Standard Plate Count	10,000 per Gram Maximum
Yeast and Mold	200 per Gram Maximum
Coliform	50 per Gram Maximum
E. Coli	Less than 10 per Gram Maximum
Coag. Pos. Staph.	Negative
Salmonella Shigella	Negative

PACKAGING

Polyethylene liner, corrugated carton.
Pack Size: 10 kgs

STORAGE REQUIREMENTS

Cool, dry storage.

SHELF LIFE

12 Months from shipping date.

Specification prepared for: _____ Date: August 25, 2000

Specification Number: N110

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