DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2001

Mr. Barry M. Tydings
President and CEO
Drug Free Enterprises, Inc.
1627 S. Granville Avenue – Suite #3
Los Angeles, CA 90025

Re: k012390
Trade/Device Name: Drug Free Enterprises NexStp Drug Check test cup
Regulation Number: 21 CFR 862.3100; 21 CFR 862.3870; 21 CFR.3150;
21 CFR 862.3610; 21 CFR 862.3250; 21 CFR.3650;
21 CFR 862.3170; 21 CFR 862.3620
Regulation Name: Amphetamine test system; Cannabinoid test system;
Barbiturate test system; Methamphetamine test system;
Cocaine and cocaine metabolite test system; Opiate test system;
Benzodiazepine test system; Methadone test system
Regulatory Class: Class II; Class II, Class II, Class II; Class II; Class II; Class II; Class II
Product Code: DKZ; DIO; LDJ; DJG; DIS; JXM; LAF; LCM; DJR
Dated: November 20, 2001
Received: November 20, 2001

Dear Mr. Nunna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) 012390

Device Name: **Drug Free Enterprises NexStp Drug Check test cup**

Indications for Use:

Drug Free Enterprises NexStp test cup is a convenient specimen collection cup and strip holder, which contains five (5) individual drug test strips for simultaneous detection of multiple drugs of abuse in human urine. The five test strips are individually encased within the wall of the device in separate chambers with no interconnections between each of the test strip. Up to nine (9) individual test strips are available for incorporation into the test device. The nine individual test strips include THC, cocaine, opiate, methamphetamine, phencyclidine, amphetamine, barbiturates, benzodiazepines, and methadone. The cut-off concentration for each of the available test strip is listed below:

THC	11 -nor-Δ^9-THC-9-COOH	50	ng/ml
COC	Benzoylecogine	300	ng/ml
OP'	Morphine	2000	ng/ml
MET	Methamphetamines	1000	ng/ml
PCP	Phencyclidine	25	ng/rnl
AMP	Amphetamines	1000	ng/ml
BAR	Secobarbital	300	ng/ml
BZO	Oxazepam	300	ng/ml
MTD	Methadone	300	ng/ml

Thomas J. Smith for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012390

Drug Free Enterprises NexStp test cup is an in vitro diagnostic device, which provide for the visual qualitative results of up to nine drugs of abuse in human urine. The test is intended for professional and point of care use . This test device in not intended for over the counter sale to lay users.

The NexStp test cup provides only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtained a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use_____
(Per 21 CFR8O1.109) (Optional Format 1-2-96)