patient labeling for the shoulder joint
metal/polymer/metal nonconstrained or
semi-constrained porous-coated
uncemented prosthesis. Use of the
preclinical section of the FDA guidance
documents can control the risks to
health of adverse tissue reaction,
infection, pain and/or loss of function,
and revision by having manufacturers
use surgical quality implant materials,
adequately test and sterilize their
devices, and provide adequate
directions for use (and patient
information).

To receive a guidance via fax
machine, telephone Center for Devices
and Radiological Health’s (CDRH) CDRH
Facts-on-Demand system at 800–399–
0381, or 301–827–0111 from a touch-
tone telephone. At the first voice
prompt, press 1 to access the Division of
Small Manufacturers Assistance Fax,
at the second voice prompt, press 2, and
then enter the document number
followed by the pound sign (#). Then
follow the remaining voice prompts to
complete your request. The guidelines
are also available from the CDRH world
wide web address at “http://
www.fda.gov/cdrh”.

IX. FDA’s Tentative Findings

FDA believes that the shoulder joint
metal/polymer/metal nonconstrained or
semi-constrained porous-coated
uncemented prosthesis should be
reclassified into class II because special
controls, in addition to general controls,
would provide reasonable assurance of
the safety and effectiveness of the
device and there is sufficient
information to establish special controls
to provide such assurance.

X. References

The following references have been
placed on display in the Dockets
Management Branch (address above)
and may be seen by interested persons
between 9 a.m. and 4 p.m. Monday
through Friday:

1. Petition for Reclassification of
Orthopedic Shoulder Prostheses submitted
by the Orthopedic Surgical Manufacturers
Association, Warsaw, IN, received July 23,
1997.
2. Transcript of the Orthopedic and
Rehabilitation Devices Panel Meeting,

XI. Environmental Impact

The agency has determined under 21
CFR 25.34(b) that this reclassification
action is of a type that does not
individually or cumulatively have a
significant effect on the human
environment. Therefore, neither an
environmental assessment nor an
environmental impact statement is
required.

XII. Analysis of Impacts

FDA has examined the impacts of the
notice under Executive Order 12866 and
the Regulatory Flexibility Act (5 U.S.C.
601–612) (as amended by subtitle D of
the Small Business Regulatory Fairness
Act of 1996 (Pub. L. 104–121), and the
Unfunded Mandates Reform Act of 1995
(Pub. L. 104–4)). Executive Order 12866
directs agencies to assess all costs and
benefits of available regulatory
alternatives and, when regulation is
necessary, to select regulatory
approaches that maximize net benefits
(including potential economic,
environmental, public health and safety
and other advantages, distributive
impacts and equity). The agency
believes that this reclassification action
is consistent with the regulatory
philosophy and principles identified in
the Executive Order. In addition, the
reclassification action is not a
significant regulatory action as defined
by the Executive Order and so is not
subject to review under the Executive
Order.

The Regulatory Flexibility Act
requires agencies to analyze regulatory
options that would minimize any
significant impact of a rule on small
entities. Reclassification of the device
from class III to class II will relieve
manufacturers of the cost of complying
with the premarket approval
requirements in section 515 of the act.
Because reclassification will reduce
regulatory costs with respect to this
device, it will impose no significant
economic impact on any small entities,
and it may permit small potential
competitors to enter the marketplace by
lowering their costs. The agency
therefore certifies that this
reclassification action, if finalized, will
not have a significant economic impact
on a substantial number of small
entities. In addition, this reclassification
action will not impose costs of $100
million or more on either the private
sector or State, local, and tribal
governments in the aggregate, and
therefore a summary statement of
analysis under section 202(a) of the
Unfunded Mandates Reform Act of 1995
is not required.

XIII. Request for Comments

Interested persons may, on or before
(insert date 90 days after date of
publication in the Federal Register)
submit to the Dockets Management
Branch (address above) written
comments regarding this document.
Two copies of any comments are to be
submitted, except that individuals may
submit one copy. Comments are to be
identified with the docket number
found in brackets in the heading of this
document. Received comments may be
seen in the office above between 9 a.m.
and 4 p.m. Monday through Friday.


Linda S. Kahan,
Deputy Director for Regulations Policy, Center
for Devices and Radiological Health.

[FR Doc. 99–13470 Filed 5–27–99; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98E–0485 and 98E–0850]

Determination of Regulatory Review
Period for Purposes of Patent
Extension; Therma Choice™ Uterine
Ballon Therapy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) has determined
the regulatory review period for Therma
Choice™ Uterine Ballon Therapy System
and is publishing this notice of
that determination as required by law.
FDA has made the determination
because of the submission of an
application to the Commissioner of
Patents and Trademarks, Department of
Commerce, for the extension of a patent
which claims that medical device.

ADDRESSES: Written comments and
petitions should be directed to the
Dockets Management Branch (HFA–
305), Food and Drug Administration,
5630 Fishers Lane, room 1061, Rockville,
MD 20852.

FOR FURTHER INFORMATION CONTACT:
Brian J. Malkin, Office of Health Affairs
(HFY–20), Food and Drug
Administration, 5600 Fishers Lane,
Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug
Price Competition and Patent Term
and the Generic Animal Drug and Patent
Term Restoration Act (Pub. L. 100–670)
generally provide that a patent may be
extended for a period of up to 5 years
so long as the patented item (human
drug product, animal drug product,
medical device, food additive, or color
additive) was subject to regulatory
review by FDA before the item was
marketed. Under these acts, a product’s
regulatory review period forms the basis
for determining the amount of extension
an applicant may receive.

A regulatory review period consists of
two periods of time: A testing phase
and an approval phase. For medical devices,
the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device ThermaChoice™ Uterine Balloon Therapy System. ThermaChoice™ Uterine Balloon Therapy System is indicated for use as a thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbirth is complete. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ThermaChoice™ Uterine Balloon Therapy System (U.S. Patent Nos. 5,105,808 and 4,949,718) from Gynelab Products, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated December 17, 1998, FDA advised the Patent and Trademark Office that this application for ThermaChoice™ Uterine Balloon Therapy System represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested FDA to determine the product's regulatory review period. FDA has determined that the applicable regulatory review period for ThermaChoice™ Uterine Balloon Therapy System is 1,031 days. Of this time, 852 days occurred during the testing phase of the regulatory review period, while 179 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: February 17, 1995. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(g)) for human tests to begin became effective on November 30, 1994. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on February 17, 1995, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): June 17, 1997. The applicant claims that the IDE was determined substantially complete for clinical studies to have begun on February 17, 1995, which represents the IDE effective date.

3. The date the application was approved: December 12, 1997. FDA has verified the applicant's claim that PMA P970021 was approved on December 12, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 446 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 27, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 24, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 1999.

Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Active Pharmaceutical Ingredient Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) in cooperation with the Association of Food and Drug Officials (AFDO) is announcing the following workshop: Active Pharmaceutical Ingredient Workshop. The workshop will address issues related to the manufacture and control of active pharmaceutical ingredients.

Date and Time: The workshop will be held on June 5, 1999, from 8 a.m. to 5 p.m. Send information regarding registration by May 27, 1999.

Location: The workshop will be held at the Adam's Mark—Riverwalk, 111 Pecan St. East, San Antonio, TX 78205, 210-354-2800 or 800-444-2326. Send information regarding registration by June 1, 1999.

Contact: AFDO, P.O. Box 3425 York, PA 17402, 717-757-2888, FAX 717-755-8089, e-mail “afdo@blazenet.net” or see the internet address “http://www.foodsafety.org/afdo” for more information.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with registration fee payable to AFDO (address above). The registration fee will be $199 for an AFDO member, $249 for a nonmember, and $449 for both workshop and AFDO conference. AFDO is charging these fees to cover its cost associated with the workshop and conference.

If you need special accommodations due to a disability, please contact AFDO at least 7 days in advance.

Dated: May 24, 1999.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 99-13559 Filed 5-27-99; 8:45 am]