

SPONDYLITIS

ASSOCIATION OF AMERICA



April 18, 2001

2001 JUL 25 10:45

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Ref: Docket # 01N-0197

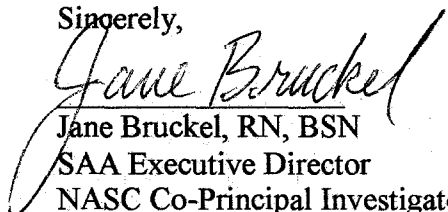
Dear Sirs,

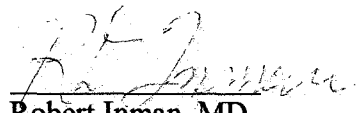
We are submitting this letter to notify the FDA of our desire to take a leadership role in the FDA Guidance Document process on ankylosing spondylitis. The Spondylitis Association of America (SAA) is a national nonprofit foundation dedicated to ankylosing spondylitis and related spondyloarthropathies. We are a major stakeholder in the outcome of these proceedings.

The SAA is integrally involved with two other groups that have interest in this process, namely the ASAS Working Group (Desiree van der Heijde, MD, PhD, Chairman) and the North American Spondylitis Consortium, NASC (John Reveille, MD, Principal Investigator).

We have convened a committee that will be responding to the five questions posed in the FDA notice. We also recommend that the first meeting be held when many of the interested parties are together in San Francisco November 11 - 15, 2001.

Sincerely,


Jane Bruckel, RN, BSN
SAA Executive Director
NASC Co-Principal Investigator


Robert Inman, MD
Chairman SAA Medical & Scientific Advisory Board
NASC Investigator

Committee Members

M.A. Khan, MD
SAA Medical and Scientific Board
ASAS Steering Committee
NASC Investigator

Patricia Newman
SAA Research Study Coordinator for NASC

Laura Schafer, RN, BSN
SAA Board of Directors

Tom West
SAA Board of Directors

David Hallegua, MD 01N-0197

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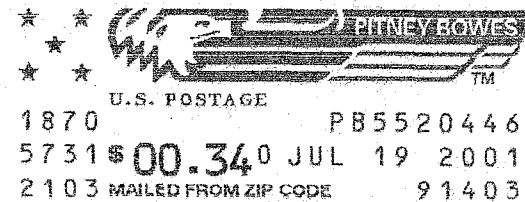
SPONDYLITIS
ASSOCIATION OF AMERICA

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