PHARMACY CERTIFICATION LETTERS
FDA Requirement: 
Pharmacy Certification Needed to Order and Dispense Tikosyn® (dofetilide)

[Date]

Dear Dr [insert last name]:

Per the Food and Drug Administration (FDA) requirements, to order and dispense TIKOSYN, retail pharmacies are required to secure a one-time certification.

TIKOSYN is indicated for the conversion to and maintenance of normal sinus rhythm (delay in the time to recurrence of atrial fibrillation/atrial flutter) in highly symptomatic patients with atrial fibrillation/atrial flutter of greater than 1 week.

The TIKOSYN Education Distribution Program, currently known as the TIKOSYN Risk Evaluation and Mitigation Strategy (REMS) is required by the FDA to ensure safe use of TIKOSYN in order to mitigate the risk of induced arrhythmia by:

- Ensuring that TIKOSYN is prescribed only by certified prescribers, and dispensed only by certified dispensers;
- Educating health care providers about the risks and the need to initiate and re-initiate therapy in a health care facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation;
- Informing patients about the serious risks associated with TIKOSYN therapy

To order and dispense TIKOSYN, you must review and follow the TIKOSYN in Pharmacy System (T.I.P.S.™) certification procedures below and enroll in the T.I.P.S. program:

- Complete the enclosed TIKOSYN Pharmacy Certification Form
- Sign and fax the form to 1-800-788-2637
- After 1 to 2 business days, confirm your certification by calling 1-877-TIKOSYN (1-877-845-6796) or visit www.tikosynlist.com. You will need to enter your pharmacy DEA number
- Your signature on the enclosed TIKOSYN certification form acknowledges that the appropriate staff members in your pharmacy are aware of the procedures for dispensing TIKOSYN
- Please post the enclosed magnetic reference piece as a reference of the T.I.P.S. program procedures and TIKOSYN contraindications in your pharmacy

Upon receipt of your certification form, a written confirmation will be sent to you.
Through pharmacy certification the pharmacy acknowledges that:

- The pharmacist will verify that a prescriber has participated in the TIKOSYN REMS and is confirmed in the Pfizer National TIKOSYN Database before dispensing
- The pharmacist will dispense a Medication Guide with each prescription

Should you have any questions regarding the certification program, please call 1-877-TIKOSYN or visit www.TIKOSYNREMS.com.

Regards,

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Regional Medical Affairs Lead, North America
Global Established Pharma, Pfizer Inc.